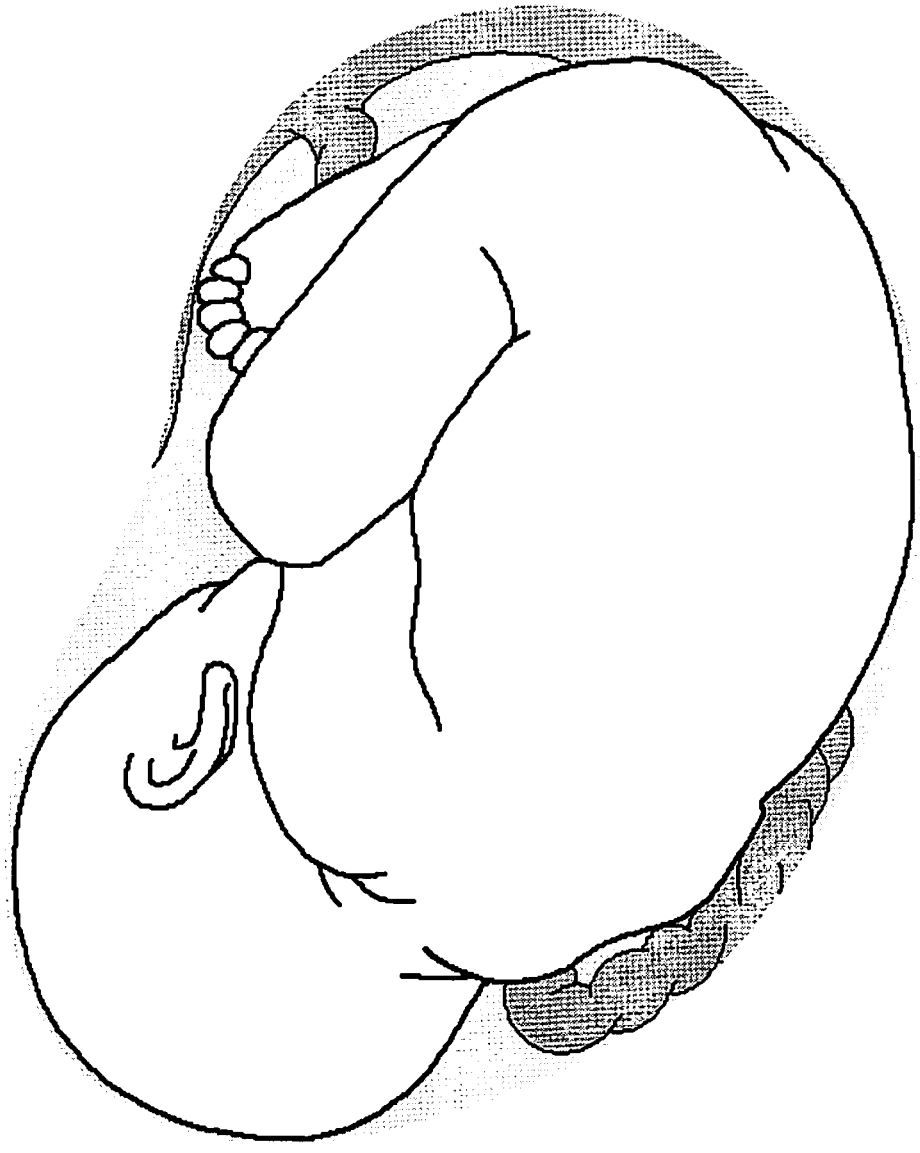
Maternal/Fetal Monitoring

CLINICAL APPLICATION

OPERATOR'S MANUAL P/N 15457AA REV. B



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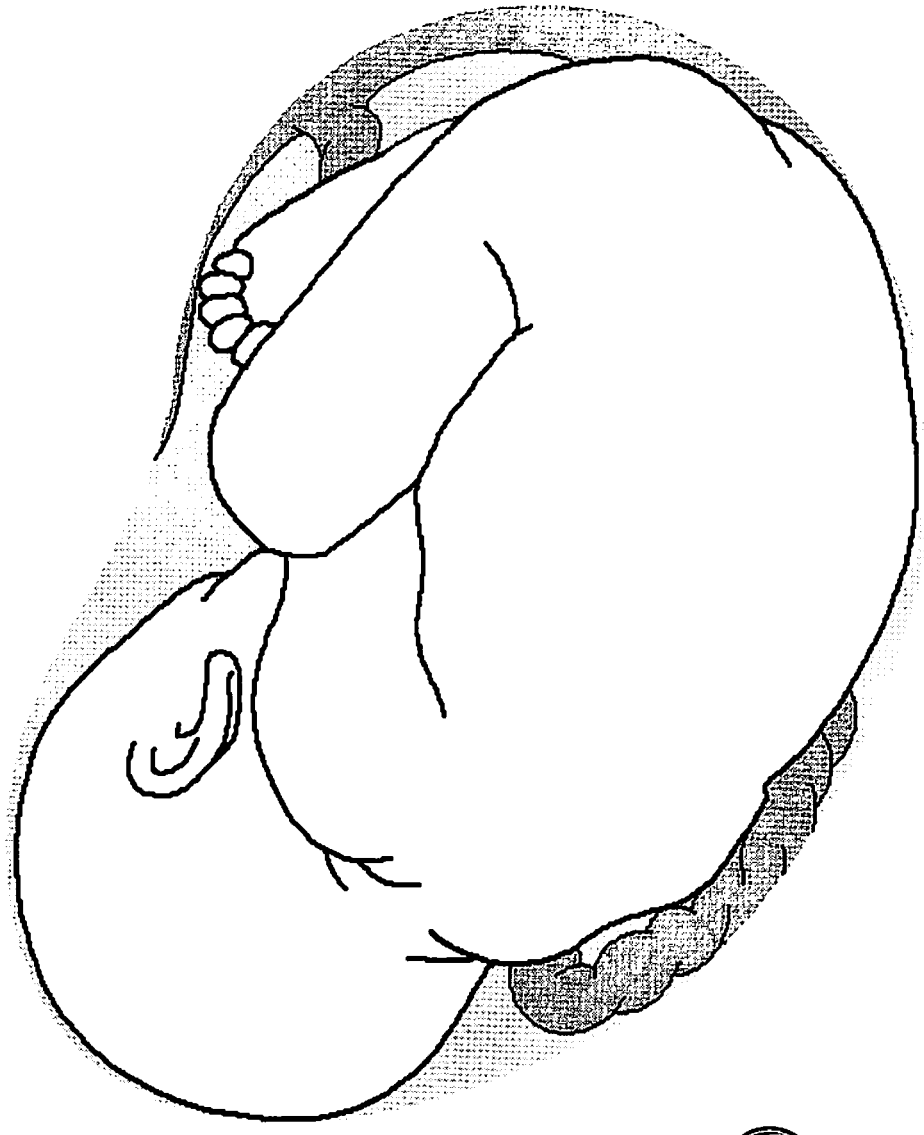

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Our obligation under this guarantee is limited to repairing, or, at our option, replacing any defective parts of our equipment, except fuses or batteries, without charge, if such defects occur in normal service.

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Revision B: 02-01

GE Medical Systems *Information Technologies* will make available on request such circuit diagrams, component diagrams, component parts lists, descriptions, calibration instructions, or other information which will assist the users or appropriately qualified technical personnel to repair those parts of the equipment which are classified by *Information Technologies* as repairable. Refer to the monitor service manual for further information.

⚠ **CAUTION:** In the United States of America, Federal Law restricts this device to sale by or on the order of a physician.

NOTICE: Purchase of a 120 Series Monitor confers no express or implied license under any Nellcor Puritan Bennett patent to use the 120 Series Monitor with any fetal oximetry sensor that is not manufactured or licensed by Nellcor Puritan Bennett.

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For your notes

Preface

About the Manual

GE Medical Systems *Information Technologies* hereinafter *Information Technologies* offers a variety of Corometrics brand fetal and maternal/fetal monitors. This "Maternal/Fetal Monitoring: Clinical Application Operator's Manual" is intended to serve as a guide in the Labor and Delivery department. The manual provides patient application instructions for Corometrics brand equipment—from the most basic antepartum fetal monitor through high-risk patient maternal/fetal monitors.

NOTE: Not all functions may be present on your monitor.

This manual should be used in conjunction with the operator's manual specific to your monitor.

Refer to the monitor's operator's manual for cleaning instructions, supplies ordering information, or troubleshooting guidelines.

For your notes

Chapter 1

⚠Safety

The information presented in this section is important for the safety of both the patient and operator and also serves to enhance equipment reliability. This chapter describes how the terms Danger, Warning, Caution, Important, and Note are used throughout the manual. In addition, *Information Technologies'* standard equipment symbols are defined.

This section includes the following important information:

General Information. 1-2
Definitions of Terminology 1-3
Warnings and Precautions. 1-4
Equipment Symbols 1-6

General Information

General Use

If the monitor is cold to the touch or below ambient temperature, allow it to stabilize before use.

To ensure patient safety, use only parts and accessories manufactured or recommended by *Information Technologies*.

Disposable devices are intended for single use only. They should not be reused.

Periodically, and whenever the integrity of the monitor is in doubt, test all functions.

Responsibility of the Manufacturer

Information Technologies is responsible for the effects on safety, reliability, and performance if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by *Information Technologies*;
- the electrical installation of the relevant room complies with the requirements of appropriate regulations; and
- the equipment is used in accordance with the instructions of use.

Definitions of Terminology

Six types of special notices are used *throughout* this manual. They are: Danger, Warning, Caution, Contraindication, Important, and Note. The warnings and cautions in this Safety section relate to the equipment in general and apply to all aspects maternal/fetal monitoring. Be sure to read the safety information in your monitor's operator's manual as well as the other chapters in this manual because there are additional warnings and cautions which relate to specific features.

When grouped, warnings and cautions are listed alphabetically and do not imply any order of importance.

Table 1-1. Definitions of Terminology

Danger	A **DANGER** notice indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
Warning	A **WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
Caution	A **CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Cautions are also used to avoid damage to equipment.
Contraindication	A **CONTRAINDICATION** describes any special symptom or circumstance that renders the use of a remedy or the carrying out of a procedure inadvisable, usually because of a risk.
Important	An **IMPORTANT** notice indicates an emphasized note. It is something you should be particularly aware of; something not readily apparent.
Note	A **NOTE** indicates a particular point of information; something on which to focus your attention.

Warnings and Precautions

Warnings

WARNINGS

CONDUCTIVE CONNECTIONS—Avoid making any conductive connections to applied parts (patient connection) which are likely to degrade safety.

CONDUCTIVE PARTS—Ensure that the conductive parts of the lead electrodes and associated connectors do not contact other conductive parts including earth.

CONNECTIONS—The correct way to connect a patient to the monitor is to plug the ***electrode leads*** into the ***patient cable*** which in turn connects to the ***monitor***. The ***monitor*** is connected to the ***wall socket*** by the ***power cord***. Do ***not*** plug the electrode leads into the power cord, a wall socket, or an extension cord.

DEFIBRILLATION—During defibrillation, all personnel must avoid contact with the patient and monitor to avoid a dangerous shock hazard. In addition, proper placement of the paddles in relation to the electrodes is required to minimize harm to the patient.

EXPLOSION HAZARD—Do not use a Corometrics maternal/fetal monitor in the presence of flammable anesthetics or inside an oxygen tent.

INSTRUCTIONS—For continued and safe use of electrical equipment, it is necessary to follow all listed instructions. However, the instructions provided in this manual in no way supersede established medical procedures concerning patient care. The monitor does not replace observation and evaluation of the patient, at regular intervals, by a qualified care provider who will make diagnoses and decide on treatments and interventions.

MRI USE—Do not use the electrodes during MRI scanning; conducted current could potentially cause burns.

WARNINGS

PATIENT CABLES AND LEADWIRES—Do not use patient cables and electrode leads that permit direct connection to electrical sources. Use only "safety" cables and leadwires. Use of non-safety patient cables and lead wires creates risk of inappropriate electrical connection which may cause patient shock or death.

SIMULTANEOUS DEVICES—Do not simultaneously connect more than one device that uses electrodes to detect ECG and/or respiration to the same patient. Use of more than one device in this manner may cause improper operation of one or more of the devices.

STRANGULATION—Make sure all patient cables, leadwires, and tubing are positioned away from the patient's head to minimize the risk of accidental strangulation.

WATER BIRTHS—Do not use a fetal or maternal/fetal monitor to directly monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water. Doing so may result in electrical shock hazard.

Cautions

CAUTION

PERFORMANCE—Report all problems experienced with equipment. If the equipment is not working properly, contact your Service Representative for service. The equipment should not be used if it is not working properly.

Equipment Symbols

The following is a list of symbols used on products manufactured by *Information Technologies*. Some symbols may not appear on your unit.

Table 1-2. Equipment Symbols	
	ATTENTION: Consult accompanying documents.
	TYPE B EQUIPMENT: Type B equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application.
	TYPE BF EQUIPMENT: Type BF equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application. Type BF equipment has an F-type applied part.
	DEFIBRILLATOR-PROOF TYPE BF EQUIPMENT: Type BF equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application. Type BF equipment is type B equipment with an F-type isolated (floating) part. The paddles indicate the equipment is defibrillator proof.
	ALTERNATING CURRENT (AC).
	EQUIPOTENTIALITY.
0	POWER OFF: disconnection from the mains.
I	POWER ON: connection to the mains.
	ON/STANDBY: button toggles between full power and standby.

Chapter 2

Introduction

This section lists the intended uses of the monitor:

Fetal Monitoring Intended Uses 2-2
Maternal Monitoring Intended Uses. 2-3
Responsibility of the User 2-4

Fetal Monitoring Intended Uses

Surveillance

Routine non-invasive and invasive fetal monitoring can be used throughout labor and delivery. Some monitors also provide a full range of advanced maternal monitoring solutions particularly for the high-risk pregnancy.

Pulse Oximetry

The 120 F-Series system continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated **as an adjunct** to fetal heart rate (FHR) monitoring in the presence of a non-reassuring fetal heart rate pattern. It should only be used after maternal membranes have ruptured and on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

IMPORTANT
Refer to "Chapter 6, Fetal Pulse Oximetry Monitoring" for contraindications, warnings, and precautions.

Maternal Monitoring Intended Uses

NOTE: Maternal vital signs provided by the monitor should only be used as an adjunct to patient assessment and must be used in conjunction with clinical signs and symptoms.

Maternal/fetal monitors measure maternal vital signs to help assess maternal well-being. A maternal/fetal monitor may be equipped to measure any combination of the following maternal vital signs:

- blood pressure
- pulse oximetry
- pulse rate
- heart rate

Blood Pressure

The monitor is intended for use in the non-invasive monitoring of maternal blood pressure (NBP). A maternal/fetal monitor is not intended for use in neonatal or pediatric blood pressure monitoring. The maternal pulse rate may also be derived from the blood pressure reading.

Pulse Oximetry

The monitor is intended for use in the non-invasive monitoring of the functional oxygen saturation of maternal arterial blood ($MSpO_2$). The maternal pulse rate may also be derived from the pulse oximetry measurement.

Heart Rate

NOTE: Maternal *heart* rate refers to data that is derived from the ECG section of the monitor while maternal *pulse* rate refers to data that is obtained from the NBP and $MSpO_2$ sections of the monitor.

The monitor is intended for use in the non-invasive monitoring of the maternal heart rate (MHR).

Responsibility of the User

A fetal or maternal/fetal monitor is intended for use by clinical professionals who are expected to know the medical procedures, practices, and terminology required to monitor obstetrical patients. This manual documents all possible parameters available in Corometrics monitors. It is the responsibility of each hospital to ensure that the Labor and Delivery staff is trained in all aspects of the selected model monitor.

The monitor is only one clinical indicator of fetal status during labor. The monitor is designed to assist the perinatal staff in assessing the status of a patient. The monitor does not replace observation and evaluation of the mother and fetus at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments or interventions. Visual assessment of the monitor display and strip chart must be combined with knowledge of patient history and risk factors to properly care for the mother and fetus.

Chapter 3

Fetal Heart Rate Monitoring

Fetal heart rate (FHR) can be measured externally using ultrasound (US or US2) or internally using a spiral electrode and legplate (FECG). In the case of twins: use two ultrasound channels; or one ultrasound channel and FECG.

This chapter describes the following monitoring methods:

Verifying the Fetal Signal 3-2
External Method (Ultrasound) 3-3
Internal Method (FECG) 3-9
Dual Fetal Heart Rate Monitoring 3-16

Verifying the Fetal Signal

Check the ***maternal*** pulse to confirm recording of FHR:

- at the onset of FHR monitoring;
- after switching FHR modes; or
- if there is an abrupt drop in heart rate (particularly if there is not a continuous trace).

External Method (Ultrasound)

Methodology

An ultrasound transducer placed on the maternal abdomen is used to direct an ultrasonic beam toward the fetal heart; the transducer detects Doppler shifted frequency changes in echoes created by moving cardiac structures. An autocorrelation process is used to determine the time interval between successive cardiac cycles.

When sound waves strike an object, they bounce back creating an echo. Ships make use of this principle with SONAR systems. These systems emit sound waves and monitor the returning echoes to locate submarines or other objects beneath the surface.

Using the same principle, the transducer emits sound waves. The sound produced has a frequency many times higher than the sound we can hear, but the ultrasonic transducer "hears" these sound waves and detects echoes from objects in their path. Of course, the object from which you want to receive echoes is the fetal heart.

The monitor also makes use of another characteristic of sound, called the Doppler principle, which states that echoes reflected by moving objects differ from those reflected by non-moving objects. This allows the monitor to recognize echoes from the fetal heart because of the heart's beating motion. The monitor also uses this beating motion to compute the fetal heart rate. This is why the transducer must be properly positioned to send sound waves toward the fetal heart in order to receive its echoes.

Sound waves at this ultrasonic frequency travel well through human tissue and liquids but travel poorly through air. Therefore, it is important to use a liquid medium (ultrasonic coupling gel) to eliminate air between the transducer and the abdomen. This helps transmit the sound waves from the transducer to the fetal heart, then back to the transducer.

When the transducer is correctly placed on the maternal abdomen and is receiving good, strong echoes from the fetal heart, the monitor can compute the FHR and present it for display and printing. Remember, however, that fetal or maternal movement can alter the position of the fetal heart rate with respect to the transducer, preventing the transducer from receiving the proper echoes.

Information Technologies offers two styles of ultrasound transducers: loop-style and button-style. Both styles are discussed in this section.

Limitations

Following the patient application procedure does not always guarantee a good FHR recording continuously throughout labor. Contractions, maternal movement, and fetal descent as labor progresses can cause the transducer to lose the signal. Fetal descent can sometimes interfere with echoes from the heart. Frequent checking of the monitor tracing and transducer position and knowledge of the patient's status in labor are necessary to maintain a good tracing.

Most of the time, a good ultrasonic tracing is maintained by properly positioning the transducer and readjusting its position when necessary. However, there is currently no *external* fetal monitoring system that has the precision of a system using *direct* fetal ECG as the signal source.

A heartbeat is composed of a sequence of movements which occur as the atria, ventricles, and valves perform their functions. The monitor may receive echoes from all of these moving parts and must interpret the series of echoes. When physiological conditions create an unusual rhythm in the returning echoes, artifacts may be produced.

The most common artifacts are double-counting and half-counting. The conditions creating these and other artifacts rarely occur. However, learning to recognize the conditions during which they are likely to occur may result in better patient management.

Whenever a counting artifact is suspected, check the fetal heart rate by auscultation and reposition the transducer, if necessary. If conditions permit, apply a spiral electrode and begin direct monitoring to obtain more precise heart rate data.

Double-Counting

NOTE: During double-counting, the audio sounds emitted from the monitor represent the *correct* heart rate.

When the FHR drops to approximately 90 BPM, heart movements gradually become so far apart that it is possible for ultrasonic monitors to interpret two heart movements belonging to a single beat as separate heartbeats—this is called *double-counting*. The FHR tracing is then double the actual heart rate. Watch for sudden changes in baseline or large jumps in heart rate during severe decelerations or bradycardia.

Half-Counting

NOTE: During half-counting, the audio sounds emitted from the monitor represent the *correct* heart rate.

When the FHR increases to 200 BPM or greater, heart movements gradually become close together. Ultrasonic monitors may interpret two separate heartbeats as individual movements belonging to a single beat—this is called *half-counting*. The FHR tracing is then half the actual rate. Look for sudden drops in baseline during tachycardia.

During contractions, both the maternal abdomen and fetus are likely to move. Either movement can cause the fetal heart rate to move out of the sound wave path, causing an erratic FHR tracing.

During periods of fetal movement, any motion of the fetus or maternal abdomen may produce echoes which interfere with those from the heart. This also can cause erratic counting or temporary loss of signal.

Variability

The ultrasound technique of recording FHR recognizes each heartbeat from a series of echoes created by moving cardiac structures. The strongest echoes may not occur at exactly the same time in every heart beat. The monitor calculates the rate using autocorrelation processing to determine the timing of successive cardiac cycles. The result may be the appearance of false short-term variability. The only way to accurately determine FHR variability, both long- and short-term, is by using a spiral electrode.

Determining the Probable Transducer Site

Keep the following in mind, when applying an ultrasound transducer:

- The clearest path to the fetal heart, using ultrasound, is usually through the fetal back.
- The fetal heart is closer to the fetal head than to the fetal buttocks.
- Choose the quadrant of the maternal abdomen which corresponds to the location of the fetal head and back (Leopold's maneuvers). For example: if the head is down and the back is facing right, choose the lower right quadrant.

Ultrasound Transducer

This section provides clinical application instructions for Corometrics loop- and button-style ultrasound transducers.

Equipment Required

The following equipment is required:

Ultrasound Transducer: ■ loop-style ■ button-style
Abdominal Belt: ■ loop-style (disposable or reusable) ■ button-style (reusable)
Ultrasound Coupling Gel

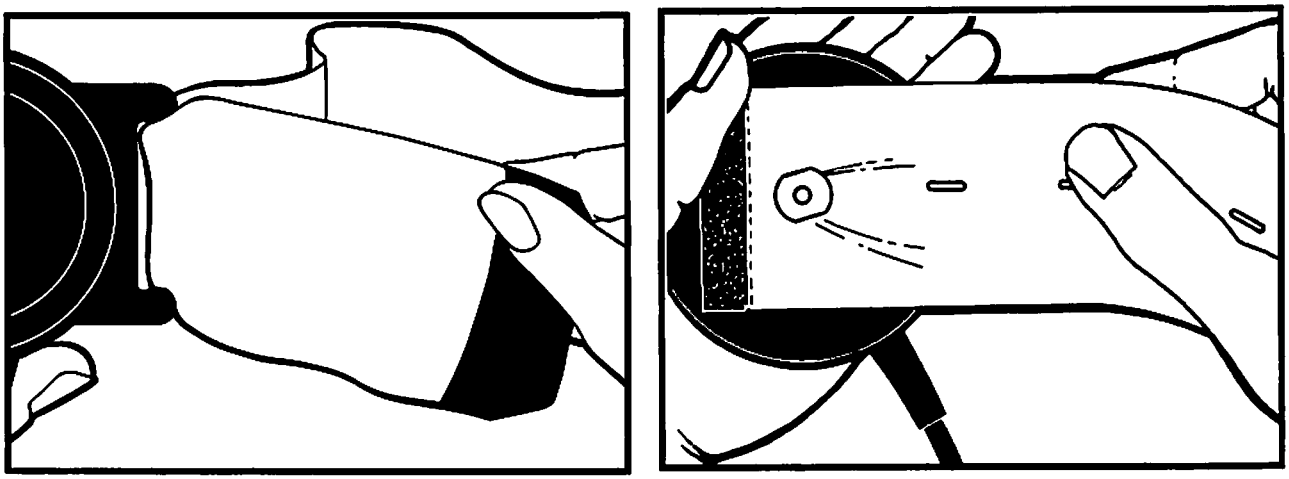
Procedure

1. Place the belt under the patient.
2. Determine the position of the fetus using Leopold's maneuvers. Determine the area from which the strongest fetal heart tones are heard. Avoid the maternal aorta. See "Determining the Probable Transducer Site" earlier in this section.
3. Plug the ultrasound transducer into the ultrasound connector.
4. Attach one end of the belt to the ultrasound transducer (see Figure 3-1):
   - ***Loop-style:*** Insert a corner of the belt through one slot on the transducer and pull it through several inches.
   - ***Button-style:*** Insert the transducer button through a buttonhole on the belt.
5. Apply a small amount of ultrasonic coupling gel to the transducer face.
6. Place the transducer face down on the maternal abdomen where the strongest heart tones are audible.
7. Adjust the volume using the monitor's volume controls.
8. Reposition the transducer as necessary until clearest heart sound is heard through the speaker.

9. Secure the other end of the belt (see Figure 3-2):
   - ***Loop-Style:*** Insert the other end of the belt through the remaining slot in the transducer and adjust to a secure, yet comfortable fit.
   - ***Button-Style:*** Button the other end of the strap to the transducer using a buttonhole that ensures a secure, yet comfortable fit.

NOTE: A temporary loss of signal causes the heartbeat indicator to stop flashing. If the sound is still clear, allow three to five seconds for the indicator to resume flashing. As labor progresses, descent of the fetus may result in a loss of signal. Reposition the transducer as necessary.

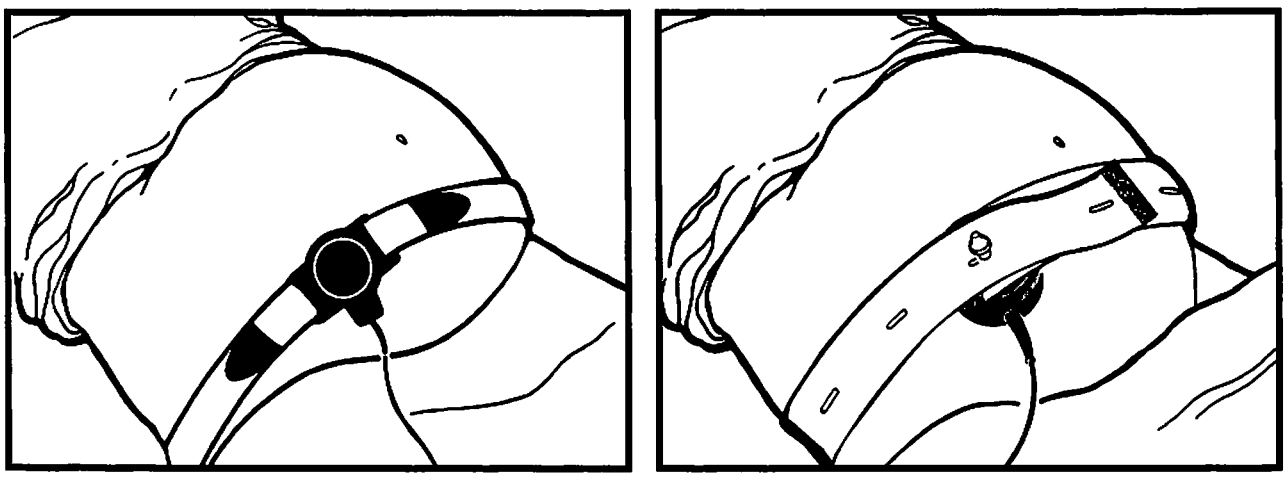
10. Three to five seconds after a clear heart sound is heard, verify that the heartbeat indicator ♡ flashes synchronously with the sound—indicating signal acceptance and recording. Note that the FHR value shows on the monitor's display and the FHR tracing appears on the top (or left) grid of the strip chart paper.



Loop-Style Transducer

Button-Style Transducer

Figure 3-1. Attaching One End of the Belt to an Ultrasound Transducer



Loop-Style Transducer

Button-Style Transducer

Figure 3-2. Securing the Other End of the Belt to an Ultrasound Transducer

Internal Method (FECG)

This method uses a spiral electrode attached directly to the fetal presenting part. The electrode is connected to the cable/legplate secured to the mother. The fetal heart rate is computed based upon the interval between successive R-wave peaks of the fetal QRS complex.

A Corometrics Intrapartum Fetal or Maternal/Fetal Monitor is compatible with a wide range of spiral electrodes each with its own application configuration. Refer to the manufacturer's packaging instructions for details on setup and patient application.

ECG Artifact Elimination

An ECG artifact elimination feature is available. (Refer to the monitor's operators manual and service manual for more information.) When ECG artifact elimination is turned *on*, the monitor will not print any new FHR value which differs by more than ±25 BPM from the previously calculated heart rate value. The printing inhibition functions on a beat-to-beat basis by comparing the last calculated rate against the newly calculated rate. The rate used for comparison purposes is always the previous rate regardless of whether this rate passed the previous ±25 BPM test. When ECG artifact elimination is turned *off*, all direct ECG rates are plotted by the recorder without regard to their deviation from previous rates. The effect of this function change is that sudden heart rate changes (such as certain arrhythmias, accelerations or decelerations) as well as artifactual changes (as when the electrode is disturbed or loosely connected) are recorded when ECG artifact elimination is turned *off*. These changes are not recorded when ECG artifact elimination is turned *on*; instead gaps in the tracing occur. This option only affects direct FECG monitoring. All other heart rate modes are unaffected by the selection.

About the Connector

NOTE: Not all monitors offer ECG monitoring.

Some monitors have a single **ECG** connector that is used for either FECG or MECG monitoring. Other monitors have a dedicated **FECG** connector for fetal ECG monitoring. For ease of reference in this manual, the **FECG** label is used to indicate fetal ECG monitoring. Refer to your monitor's operator's manual for the actual connector label(s).

Safety Precautions

The following safety precautions refer to direct fetal heart rate monitoring:

WARNING

ELECTRODE REMOVAL—Do not pull the electrode from the fetal skin. Do not remove the electrode by pulling the wires apart.

CAUTIONS

ASEPTIC CONDITIONS—Direct monitoring should only be used under aseptic conditions.

RUPTURED MEMBRANES—Membranes must be ruptured prior to introduction of the spiral electrode.

CONTRAINDICATION

SPIRAL ELECTRODE PLACEMENT—Do not apply the spiral electrode to the fetal face, fontanels, or genitalia; when placenta previa is present; when genital infections (e.g., herpes, Group B streptococcus, gonorrhea), maternal hepatitis, or maternal acquired immune deficiency syndrome (AIDS) exist; when the mother is a confirmed carrier of hemophilia and the fetus is either affected or of unknown status; or when it is not possible to identify the portion of the fetal body where application is contemplated.

Using a Disposable Legplate Attachment Pad (Strapless Method)

The following instructions describe the recommended *strapless method* of patient attachment using a disposable legplate attachment pad.

Equipment Required

The following equipment is required:

Spiral Electrode (applied)
Spiral Legplate
Spiral Disposable Legplate Attachment Pad

Procedure

1. Use alcohol wipe(s) to clean the attachment area on the patient's lower abdomen or upper thigh. Allow to air dry.
2. Remove the disposable legplate attachment pad from its packaging.
3. Connect the attachment pad to the underside of the legplate by pushing them together until they snap in place.

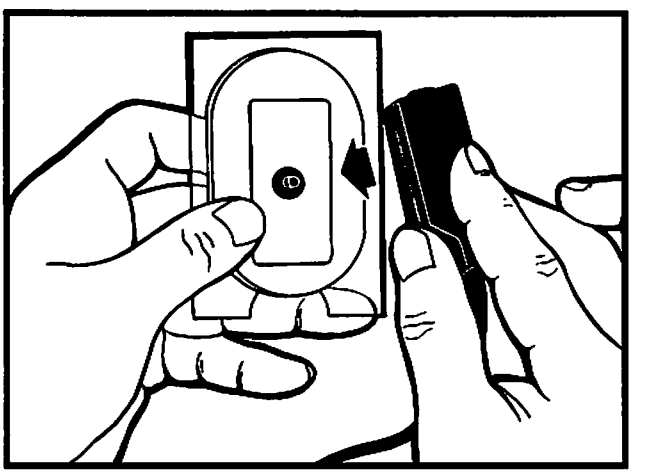


Figure 3-3. Connecting the Attachment Pad to the Legplate

4. Carefully remove the protective backing from the pad.
5. Apply the attachment pad and legplate to the desired site. Use your fingers to press it securely in place.

6. Wipe clean the attachment end of the applied spiral electrode before inserting it into the legplate. Make certain the plug is fully inserted into the mating receptacle of the legplate.

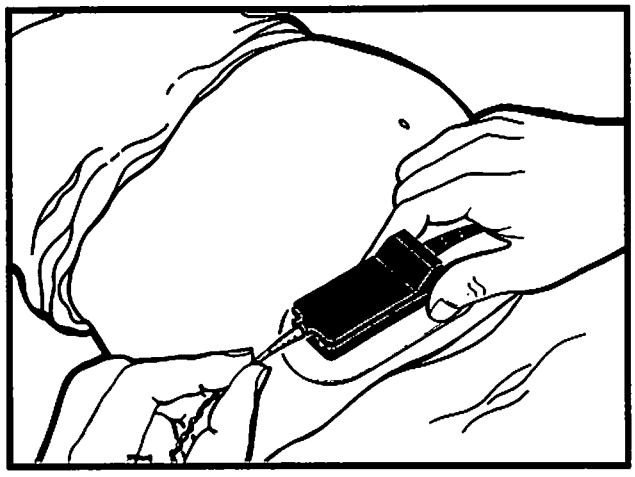


Figure 3-4. Attaching the Spiral Electrode to the Legplate

NOTE: It may be necessary to tape the legplate cable to the patient in order to prevent excessive tension on the legplate or the attachment pad.

7. Plug the legplate into the **FECG** connector on the monitor. Note that the FHR value shows on the monitor's display and the FHR tracing appears on the top (or left) grid of the strip chart paper.

Using a Legplate and Strap (Strap Method)

The following instructions describe the method of patient attachment using a strap adapter and a reusable* legplate strap.

Equipment Required

The following equipment is required:

Spiral Electrode (applied)
Spiral Legplate
Spiral Legplate Strap Adapter
Legplate Strap (disposable or reusable)
ECG Conductive Cream

Procedure

1. Connect the strap adapter to the underside of the legplate by pushing them together until they snap in place.

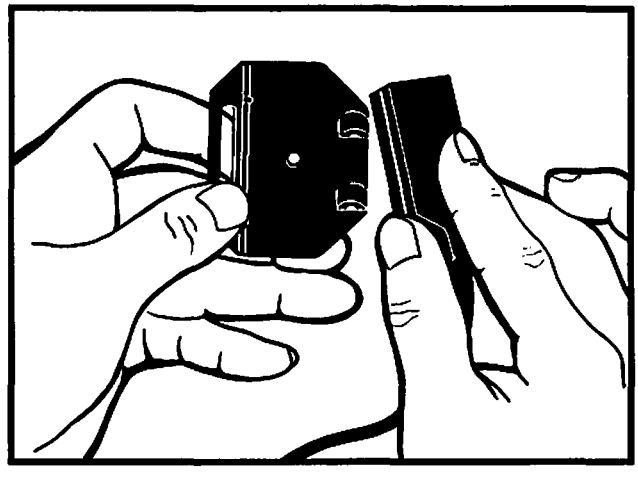


Figure 3-5. Connecting the Strap Adapter

2. Attach the strap to the legplate adapter by inserting the plastic clip into the hinge holes on one end of the adapter, keeping the Velcro side facing you.

* *This manual provides instructions for using the reusable strap only. Instructions for using the disposable straps are printed on the package.*

NOTE: The recommended placement position for the legplate is on the top of the *upper* thigh, instead of the inner thigh. The placement of the legplate in this position minimizes fluid contacting the legplate resulting in easier transducer cleaning between patient uses.

3. Apply conductive cream to the contact surface of the legplate adapter and place it on the thigh of the patient.

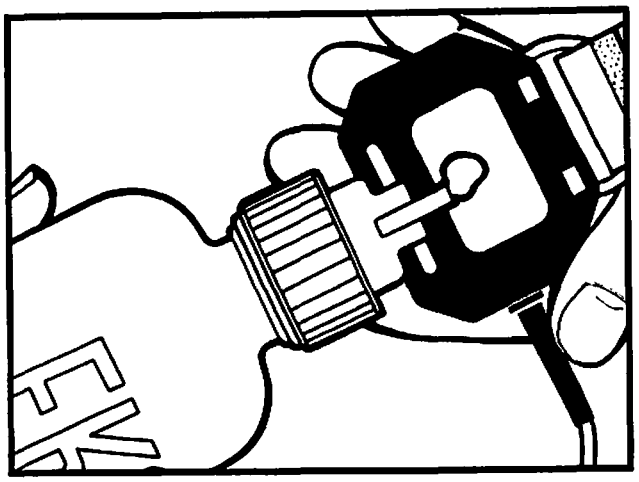


Figure 3-6. Applying Conductive Cream

4. Pass the legplate strap around and under the patient's thigh and then through the slot in the adapter. Fold the strap back onto itself so the Velcro adheres.

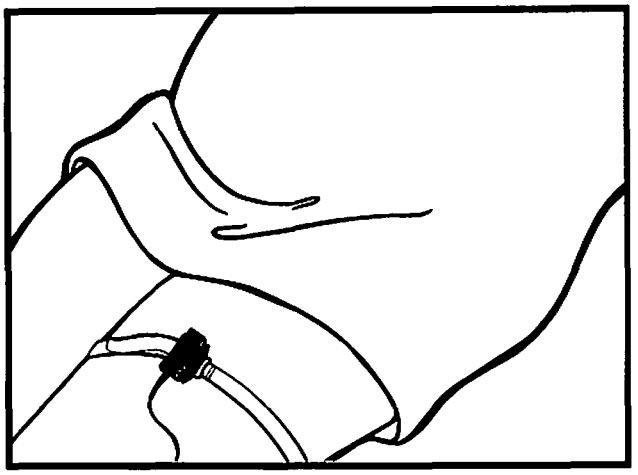


Figure 3-7. Securing the Legplate Strap

5. Wipe clean the attachment end of the applied spiral electrode before inserting it into the legplate. Make certain the plug end is fully inserted into the mating receptacle of the legplate.
6. Plug the legplate into the monitor's **FECG** connector. Note that the FHR value shows on the monitor's display and the FHR tracing appears on the top (or left) grid of the strip chart paper.

Removing a Spiral Electrode

Remove the spiral electrode and legplate as follows:

1. Remove the attachment end of the spiral electrode from the legplate.
2. To remove the spiral electrode: grasp the electrode wires as close to the fetal presenting part as possible; twist counterclockwise until free from the presenting part.

> **CAUTION**
> ELECTRODE REMOVAL—Do not pull the electrode from the fetal skin. Do not remove the electrode by pulling the wires apart. Refer to the manufacturer's product packaging for detailed instructions.

3. Remove the attachment pad or the legplate strap as follows:
   - ***Disposable Attachment Pad:*** Detach the legplate from the disposable attachment pad. Carefully peel off the attachment pad using the non-adhesive tab portion of the pad. Discard the attachment pad.
   - ***Legplate Strap:*** Unfasten the legplate strap to remove the legplate/adapter from the patient.

Dual Fetal Heart Rate Monitoring

Dual fetal heart rate monitoring is accomplished using:

- two ultrasound transducers; or
- one spiral electrode and one ultrasound transducer.

External Monitoring of Twins (Dual Ultrasound)

This section explains how to monitor twins using two ultrasound transducers.

IMPORTANT
To guard against mode changes *prior to delivery* of the presenting twin: use the primary ultrasound connector for the presenting twin; use the secondary ultrasound connector for the second twin. When switching to FECG for the presenting twin, disconnect the primary ultrasound connector which is no longer in use.

1. Apply an ultrasound transducer ***over the presenting twin***. Plug the ultrasound transducer into the monitor's primary ultrasound connector. Refer to page 3-6 through page 3-8 for patient application information.
2. Apply a second ultrasound transducer ***over the second twin***. Plug the ultrasound transducer into the monitor's secondary ultrasound connector.

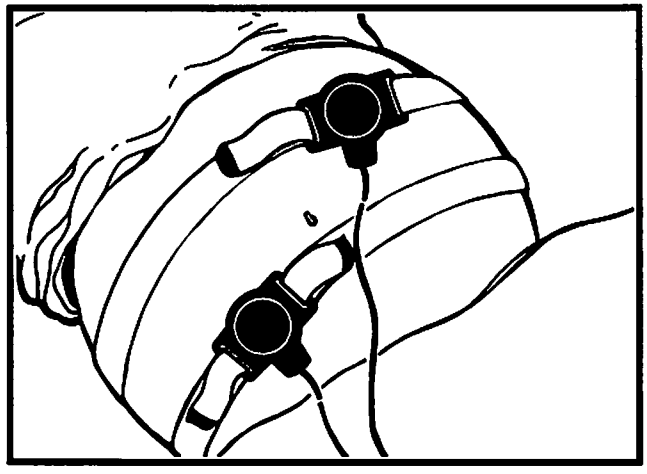


Figure 3-8. Placing the Secondary Ultrasound Transducer

NOTE: Refer to your monitor's operator's manual for more information about FHR displays and trend representations.

3. Note that the tracing derived from the primary ultrasound transducer prints in plain back and is annotated with US ~^^. The tracing derived from the secondary ultrasound transducer prints in bold and is annotated with **US2** ~^^.

Internal/External Monitoring of Twins (FECG/Ultrasound)

NOTE: Refer to your monitor's operator's manual for more information about FHR displays and trend representations.

1. Plug an ultrasound transducer into the ultrasound connector. (For monitors which support dual ultrasound *and* FECG, use the **US2** connector.)
2. Plug the legplate into the **FECG** connector.
3. Apply the ultrasound transducer as described earlier on page 3-6 through page 3-8; apply the spiral electrode as described earlier on page 3-11 through page 3-14.

IMPORTANT
At the commencement of dual external heart rate monitoring, use the primary ultrasound connector to monitor the presenting twin; use the secondary ultrasound connector for the second twin. As soon as FECG is employed for the presenting twin, you must take care to unplug the ultrasound transducer that was monitoring the presenting twin (primary connector) which now has the spiral electrode in place. In the event that both ultrasound transducers are left connected and the FECG mode of monitoring is employed, the FHR derived from the **FECG** connector overrides the primary ultrasound connector.

4. Note that the tracing derived from FECG prints in plain back and is annotated with FECG ~^^ on the strip chart paper. The tracing derived from the ultrasound transducer prints in bold and is annotated with **US** ~^^ (or **US2** ~^^ depending on your model monitor and the connector being used).

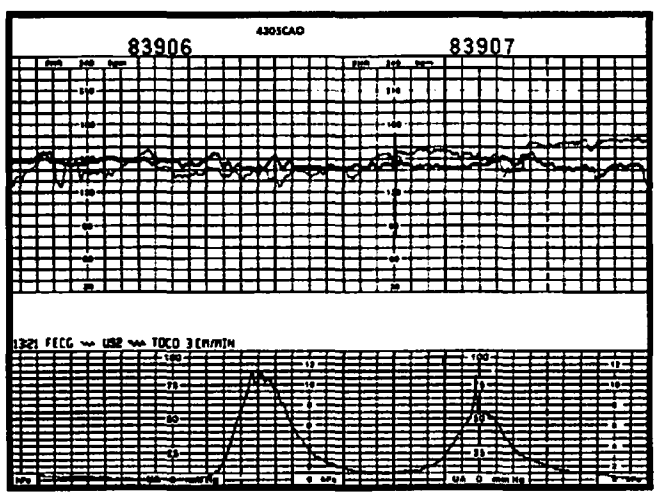


Figure 3-9. Recording Dual Heart Rates

Heartbeat Coincidence

Some monitors have a feature called heartbeat coincidence which indicates the possibility that you may be monitoring a duplicate signal. Refer to your monitor's operator's manual for detailed information.

Fetal Heart Rate Offset Mode

When monitoring twins, overlapping traces may be difficult to interpret. Many Corometrics monitors provide a +20 BPM shift for the secondary FHR trend to alleviate this problem—whether using dual ultrasound or ultrasound and FECG.

Enabling/Disabling the Fetal Heart Rate Offset Mode.

For information on enabling the heart rate offset mode, refer to the monitor's operator and service manuals. *Enabled* and *activated* do not mean the same thing. When the option is enabled you then have the capability to *activate* and *de-activate* the function as needed.

Activating the FHR Offset

When you activate the heart rate offset mode, the secondary FHR trend is shifted +20BPM.

If using dual ultrasound, or US2 and FECG, the US2 trace shifts +20 BPM and the US2+20 symbol prints on the upper portion of the top grid. If using the primary ultrasound connector and FECG, the ultrasound trace shifts +20 BPM and the US + 20 symbol prints on the upper portion of the top grid. (See Figure 3-10.)

A vertical dashed line prints to draw your attention to the shifted trend. On some monitors, a right arrow (→) prints at the top and bottom of the dashed line.

De-activating the FHR Offset Mode

After the FHR patterns have been assessed, set the secondary FHR trend back to the normal (unshifted) mode:*

NOTE: If the auto-revert (10 MIN) feature is enabled, the shifted heart rate trace automatically reverts to normal after the 10-minute timer expires.

A vertical dashed line prints to signify that the trend has been returned to the unshifted position. On some monitors, a left arrow (←) prints at the top and bottom of the dashed line.

* *Setting the FHR trend to the normal (unshifted) mode does not disable the HR Offset function; it de-activates it. To disable the mode, refer to the operator's manual for your monitor.*

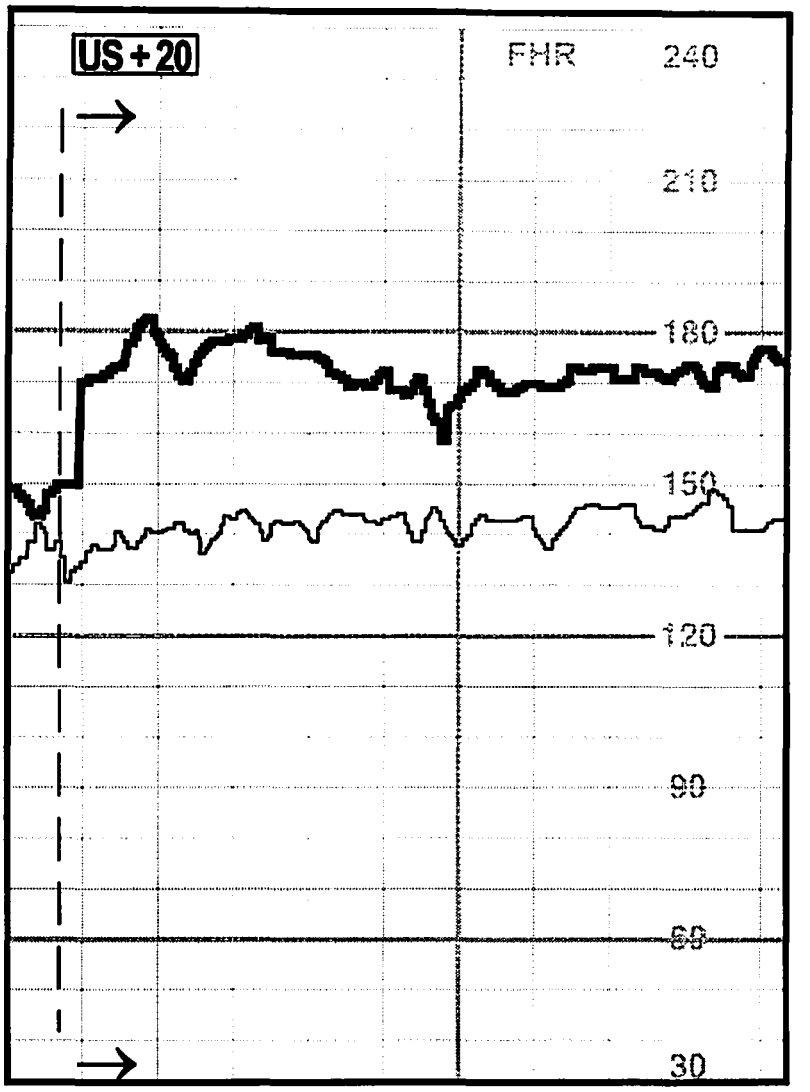


Figure 3-10. Fetal Heart Rate Offset Strip Example

For your notes

Chapter 4

Fetal Movement Detection

Fetal movement detection is an *option* which can be installed in some monitors. Contact your Service Representative for information about availability.

This chapter describes the sensor placement application.

Limitations 4-2
Strip Chart Annotation 4-3
Using the Remote Event Marker to Complement the Patient Record 4-4

Limitations

Fetal movement detection (FMD) is designed to detect *gross* fetal body movements and body movements with associated limb movement. *Information Technologies* defines *gross fetal body movement* as the "extension, flexion, or rolling over of the fetal trunk about the longitudinal axis of the body and associated limb movements." Movements of the extremities alone *may not* be detected. Eye movements *will not* be detected.

CAUTION
FALSE DETECTION—The following may be automatically detected as fetal movement: transducer movement and maternal movement such as coughing, laughing, repositioning, mother poking her abdomen, in addition to emesis, fetal hiccups, or twins. During fetal sleep, or in the event of a fetal demise, some of these detected movements may be confused with fetal movement.

Strip Chart Annotation

When fetal movement detection is *enabled*, the mode annotation **FMD** - — prints in the center margin.

When fetal movement is *detected*, a solid line automatically prints on the bottom of the top grid for the duration of the detected movement.

Using the Remote Event Marker to Complement the Patient Record

NOTE: Not all monitors offer the FM marker type.

The Remote Event Marker prints an arrow (↑ or FM↑) on the strip chart paper to record an "event" such as fetal movement. Refer to your monitor's operator's manual for instructions on setting the marker type.

The Remote Event Maker can be used, no matter what the annotation, to complement the patient record:

1. Plug the Remote Event Marker into the monitor's rear panel connector labeled **Remote Marks ↑**.
2. Instruct the mother to press the button on the Remote Event Marker whenever she feels fetal movement. Instruct her to hold down the button for the duration of the perceived fetal movement.
3. The annotation, ↑ or FM↑, prints on the strip chart in addition to a horizontal bar for as long as the Remote Event Marker button is held down (e.g. FM↑___).

Chapter 5

Uterine Activity Monitoring

Maternal uterine activity can be measured externally using a tocotransducer or internally using a fluid filled catheter or a transducer-tipped catheter.

This chapter describes the following monitoring methods:

External Method (Tocotransducer) 5-2
Internal Method (IUPC). 5-7

External Method (Tocotransducer)

A tocotransducer applied to the maternal abdomen records relative changes in abdominal tension caused by uterine contractions.

Information Technologies offers tocotransducers in two styles: loop-style and button-style.

IMPORTANT
FOR TRIMLINE TOCOTRANSDUCERS ONLY—You must wait at least ten seconds from the time you power the monitor on or connect a tocotransducer before pressing the **UA Reference** pushbutton.

Establishing a Baseline

Monitoring uterine activity using a tocotransducer provides ***relative*** pressure measurements—compared to a baseline or UA reference. The quality of measurements depends on each of the following:

- position of the tocotransducer
- belt tension
- size of the patient
- established baseline

All Corometrics monitors provide a **UA Reference** pushbutton which is used to set the baseline. When a baseline is established, all pressure measurements are relative to that baseline. The baseline can be set manually by two different methods or automatically, when necessary. Whenever the baseline is set, whether manually or automatically, the strip chart is annotated with **UA REF**.

Initial Referencing

For Trimline Tocotransducers only, it is important to establish an initial baseline when the tocotransducer is plugged into the monitor *but not yet applied to the patient*. In other words, when no pressure is applied to the transducer button.

For other transducers, the initial reference automatically occurs. After you plug in a transducer, verify that the display reads less than 30 relative units. Make a note of the reading.

The purpose of establishing a baseline at this point is necessary for consistency when applying and tightening the belt. You will have to set the baseline again, after tightening the belt.

Accounting for Belt Tension

When you adjust the belt on the patient, regardless of tocotransducer type, you want to ensure a comfortable fit; you also want to ensure that the transducer is held securely in place. *Information Technologies* recommends adjusting the belt tension so that, between contractions, the UA display shows approximately 25 relative units ***above*** the initial baseline.

After the belt is adjusted, it is important to establish a new baseline—to distinguish the belt pressure from actual uterine pressure. Also, the pressure readings could tend to go off the scale if you do not account for the belt tension. (Remember, only press the **UA Reference** button between contractions.)

More About Referencing

Out of Range Condition

After you press the **UA Reference** button, if there is insufficient range to provide at least 100 relative units above the reference level (probably because the belt is too tight), the UA display indicates a "CHECK TOCO" condition. Some monitors show a flashing + sign; some monitors flash "+199" in the display; while others display the message **CHECK TOCO**. Refer to your monitor's operator's manual for details about how this condition is indicated. If this happens, remove the tocotransducer from the patient; re-reference with no pressure applied to the button; re-apply the transducer to approximately 25 relative units ***above*** the baseline; then re-reference one more time. If you still receive the error, try a different tocotransducer or contact your Service Representative.

Manually Setting the Baseline at the Default Value

A momentary press on the **UA Reference** pushbutton sets the baseline at the *default* setting. All monitors are shipped with a *default* setting of 10 relative units. For most monitors, this default setting cannot be re-defined. On newer monitors, qualified service personnel can access a service screen to re-define the baseline *default* to 5, 10, 15, 20, or 25 relative units.

Manually Overriding the Baseline Default Value

Pressing the **UA Reference** pushbutton for more than two seconds causes the UA reference level and display to override the default setting and cycle through all available selections: 5, 10, 15, 20, or 25 relative units, starting at the default setting—until the button is released. Once the button is released, the UA trace and UA value take on this new value as a baseline for reference.

Momentary depression of the **UA Reference** pushbutton reverts back to using the *default* setting (usually 10 relative units).

Automatic Baseline "Zeroing"

If pressure falls below 0 relative units (probably because the belt has loosened), automatic UA referencing occurs and a new baseline reference is set at 0 relative units.

Tocotransducer Patient Application

This section discusses uterine activity monitoring using a tocotransducer.

Equipment Required

You will need the following items:

Tocotransducer: ■ (loop-style) ■ (button-style)
Abdominal Belt: ■ loop-style (disposable or reusable) ■ button-style (reusable)

Procedure

1. Attach one end of the belt to the tocotransducer:
   - ◆ ***Loop-Style:*** Insert a corner of the belt through one slot on the transducer and pull it through several inches.
   - ◆ ***Button-Style:*** Insert the transducer button through a buttonhole on the belt.
2. Insert the transducer cable plug into the monitor's **UA** connector.

IMPORTANT
TRIMLINE TOCOTRANSDUCERS ONLY—You must wait at least ten seconds before pressing the **UA Reference** pushbutton following: powering on the monitor; or connecting/re-connecting the tocotransducer to the **UA** connector.

3. This step depends on the transducer type:

- ■ ***Trimline Tocotransducers:*** Hold the transducer so that the pressure sensor faces up and no pressure is applied; then press the **UA Reference** pushbutton to set the UA baseline. (Refer to "Establishing a Baseline" on page 5-2.)
- ■ ***Other Tocotransducers:*** Observe the UA reading on the display. Ensure the value is less than 30 BPM and make a note of the value.

4. Position the tocotransducer on the maternal abdomen over the uterine fundus or where there is the least maternal tissue and the contractions are strongly detected during palpation.

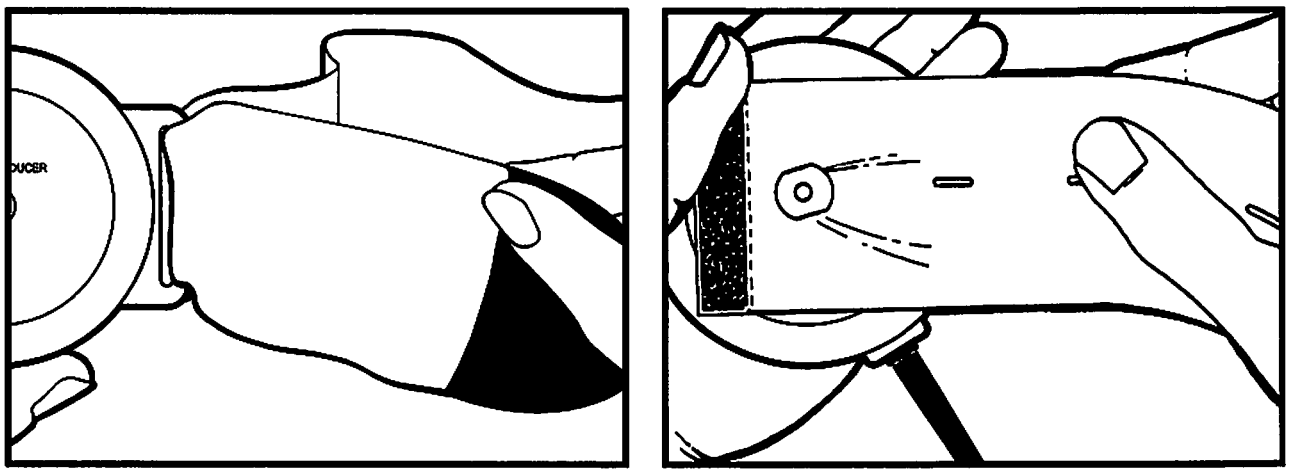
5. Secure the other end of the belt to ensure a comfortable fit that holds the transducer in place (see Figure 5-2).

   - ***Loop-Style:*** Insert the other end of the belt through the remaining slot in the transducer and adjust to a secure yet comfortable fit.
   - ***Button-Style:*** Button the other end to the belt to the transducer using a buttonhole that ensure a secure yet comfortable fit.

   Information Technologies recommends tightening the belt until the UA display shows approximately 25 relative units ***above*** the baseline—between contractions. *For example:* If the baseline is set to 10 relative units in step 3, tighten the belt until the UA display shows approximately 35 relative units between contractions.

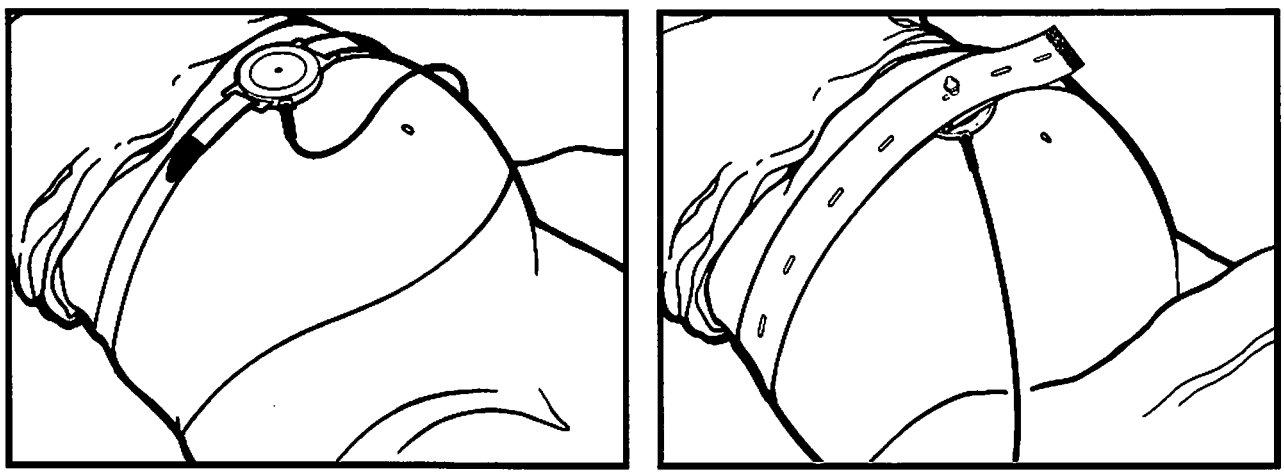
6. Between contractions, use the **UA Reference** pushbutton to set the baseline again—to compensate for the pressure caused by the belt tension. (Refer to "Establishing a Baseline" on page 5-2.)

7. Note that the UA value shows on the monitor's display and the UA tracing prints on the bottom (or right) grid of the strip chart paper.



Loop-Style Transducer | Button-Style Transducer

Figure 5-1. Attaching One End of the Belt to the Tocotransducer



Loop-Style Transducer | Button-Style Transducer

Figure 5-2. Securing the Belt to the Tocotransducer

Internal Method (IUPC)

A catheter inserted transcervically into the uterine cavity measures intrauterine pressure. A Corometrics Fetal or Maternal/Fetal Intrapartum Monitor accepts a wide range of catheters from many manufacturers. Refer to the manufacturer's packaging instructions for details on setup and use of the IUPC.

Cautions for Use

The following safety information applies to intrauterine pressure monitoring:

CAUTIONS

ASEPTIC CONDITIONS—Direct monitoring should only be used under aseptic conditions.

CATHETER INSERTION—When inserting an intrauterine catheter, do not force the catheter guide or catheter since it is possible to perforate the uterus.

RUPTURED MEMBRANES—Membranes must be ruptured prior to introduction of the intrauterine catheter.

Why You Must Zero the System

When you zero the system, you are referencing the pressure to 0 mmHg while the system is open to air to ensure an absolute pressure measurement.

The following are examples when you would rezero your IUPC system. Refer to the manufacturer's packaging instructions for details on how to zero your IUPC system.

- If you disconnect the patient from the monitor all zeroing information is lost. If you re-connect the patient to the monitor you must re-zero—regardless of whether you connect to the same monitor or a different monitor.
- If the mother's position has changed so that the height of the maternal xiphoid has changed in relation to the position of the strain gauge in fluid-filled catheter systems, the baseline may have been altered. If this is the case, adjust the height of the strain gauge and re-zero.
- If there is insufficient compensation to provide 100 mmHg above the reference level. Re-zeroing should correct the problem.
- If a negative value is displayed (pressure less than 0 mmHg), the baseline should be re-zeroed. (When a negative value occurs for more than 20 seconds, the message **BASELINE PRESSURE OFFSCALE** prints on the strip chart paper.)

Chapter 6

Fetal Pulse Oximetry Monitoring

A maternal/fetal monitor equipped with built-in fetal oximetry measures fetal oxygen saturation ($FSpO_2$) using the principles of spectrophotometry and plethysmography.

This chapter is intended to serve as a guide in the Labor and Delivery Department for the use of the $FSpO_2$ feature of your Corometrics maternal/fetal monitor. This chapter is intended to introduce the user to the proper method of inserting the sensor, the criteria for placing the sensor, and the management of patients who have the sensor in place. This manual should also be used in conjunction with the operator's manual specific to your monitor. Refer to your operator's manual for troubleshooting information.

In addition, your monitor is also accompanied by the "Information for Prescribers" which describes the randomized clinical trial performed to support the use of $FSpO_2$ monitoring during labor and delivery. The guidelines listed in "Placement Criteria and Patient Management" on page 6-6 for when to place a sensor and how to manage a patient once the sensor is placed are the guidelines used in the randomized controlled clinical trial.

This chapter describes the sensor placement application.

Indications, Contraindications, Warnings, and Precautions 6-2
Placement Criteria and Patient Management 6-6
System Overview 6-10
Patient Application 6-15

Indications, Contraindications, Warnings, and Precautions

Indications for Use

The 120 F-Series system continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated **as an adjunct** to fetal heart rate (FHR) monitoring in the presence of a non-reassuring fetal heart rate pattern. It should only be used after maternal membranes have ruptured and on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks. (This is further defined in the Sensor Placement Criteria located in this manual on page 6-6.)

$FSpO_2$ Contraindications

CONTRAINDICATION

PATIENT CONDITIONS—Use of the $FSpO_2$ feature is contraindicated in patients with any of the following conditions:

- Documented or suspected placenta previa
- Ominous FHR pattern requiring immediate intervention
- Need for immediate delivery (unrelated to FHR pattern), such as active uterine bleeding.

$FSpO_2$ Warnings

WARNINGS

INDICATIONS FOR USE—The 120 F-Series System continuously monitors intrapartum fetal oxygen saturation ($FSpO_2$) and is indicated **as an adjunct** to fetal heart rate(FHR) monitoring in the presence of a non-reassuring heart rate pattern. It should only be used after maternal membranes have ruptured on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

ELECTROSURGICAL EQUIPMENT—Do not use the $FSpO_2$ feature while using an Electrosurgical Unit (ESU). Remove the fetal oxygen sensor from the mother and fetus before using an ESU. An improperly grounded ESU can cause surface skin burns on the fetus if both the monitor and an ESU are used together.

EXPLOSION HAZARD—Do not use the monitor in the presence of flammable anesthetics or inside an oxygen tent. Such use may constitute a fire or explosion hazard.

WATER BIRTHS—Do not use the monitor to directly monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water. Doing so may result in electrical shock hazard.

INTERFACING OTHER EQUIPMENT—Monitoring equipment must be interfaced with other types of medical equipment by qualified biomedical engineering personnel. Be certain to consult manufacturer's specifications to maintain safe operation.

MATERNAL INFECTIONS—Do not use the $FSpO_2$ feature in women with active genital herpes or other infection precluding internal monitoring. Insertion of the fetal oxygen sensor in these women may result in transmission of pathogens to the fetus.

MATERNAL HIV—Do not use the $FSpO_2$ feature in women who are seropositive for human immunodeficiency virus (HIV). Insertion of the fetal oxygen sensor in these patients may result in fetal exposure to the virus.

MATERNAL HEPATITIS—Do not use the $FSpO_2$ feature in women who are seropositive for Hepatitis B and/or Hepatitis E. Insertion of the fetal oxygen sensor in these patients may result in fetal exposure to these antigens.

$FSpO_2$ Precautions

Clinical Use Precautions

CAUTIONS

TRAINING—Physicians and other licensed practitioners who use the $FSpO_2$ feature should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in fetal scalp electrode and intrauterine pressure catheter placement.

DILATION AND ROM—Do not attempt to insert the sensor if the patient is dilated less than 2 cm or if amniotic membranes have not ruptured. Doing so may result in erroneous $FSpO_2$ measurements and/or patient injury. Do not attempt to rupture amniotic membranes with the sensor. Doing so may result in patient injury and/or sensor malfunction.

OPERATIVE/ASSISTED DELIVERY—Do not leave the fetal oxygen sensor in place during vacuum extraction, forceps delivery, or Cesarean delivery. Doing so may result in patient injury. Remove the fetal sensor before commencing any form of operative delivery.

STYLET USE—Never attempt to reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may tear the stylet channel and expose the stylet which might result in serious patient injury. Sensor adjustments can be accomplished without the stylet.

SENSOR ACCURACY—Suboptimal sensor placement, excessive vernix, fetal hair, or motion artifact (due to uterine contractions or maternal position changes), may result in no $FSpO_2$ values being displayed, or erroneous $FSpO_2$ values.

FETAL BRADYCARDIA—If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.

DEFIBRILLATION—Do not leave the fetal oxygen sensor in place during defibrillation. **Even though the sensor manufacturer's package labeling indicates that the sensor may be left in place during defibrillation, the sensor should be removed when used with a Corometrics monitor.**

MRI EQUIPMENT—Do not use a monitor or fetal oxygen sensor during MRI scanning. Strong magnetic fields may affect the device causing erroneous $FSpO_2$ measurements.

Technical Precautions

CAUTIONS

SENSOR TYPE—Do not attempt to use any sensor other than sterile, single-use Nellcor Fetal Oxygen Sensors (FS14 Series) with a Corometrics Monitor. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous $FSpO_2$ measurements, and/or patient injury.

DAMAGED EQUIPMENT—Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous $FSpO_2$ measurements.

CLEANING/STERILIZATION—Never attempt to clean, reprocess, or resterilize fetal oxygen sensors. Doing so may result in sensor malfunction, erroneous $FSpO_2$ measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oxygen sensor is supplied (by Mallinckrodt, Inc.) as a sterile, single-use, disposable device.

SERVICING—Do not remove the monitor cover or attempt to service this monitor yourself. Only qualified service personnel should attempt servicing this equipment. Refer servicing to an *Information Technologies* Service Representative.

SENSOR IMMERSION—Do not immerse the sensor completely in liquid (the plug is not waterproof). Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous $FSpO_2$ measurements.

PATIENT MODULE IMMERSION—Do not immerse the fetal patient module completely in liquid— the unit is not waterproof. Fluid damage to the module may result in malfunction and/or erroneous $FSpO_2$ measurements.

Placement Criteria and Patient Management

Sensor Placement Criteria

The patient should be in active labor (dilation ≥ 2 cm, vertex –2 station or lower) with ruptured membranes. The placement of the Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14) is appropriate if the fetal heart rate tracing shows evidence of one or more the following non-reassuring FHR patterns:

- Baseline FHR between 100–110 BPM, with no accelerations > 15 BPM for more than 15 seconds
- Baseline FHR < 100 BPM with accelerations
- Increased variability > 25 BPM for > 30 minutes
- Mild or moderate variable decelerations for > 30 minutes
- Late decelerations (at least 1 per 30 minutes)
- Decreased variability < 5 BPM for > 30 minutes
- Persistent late decelerations (> 50% of contractions) for > 15 minutes
- Tachycardia > 160 BPM with long-term variability < 5 BPM
- Sinusoidal pattern
- Variable decelerations with any of the following:
  - A relative drop of ≥ 70 BPM or an absolute drop to ≤ 70 BPM for 60 seconds
  - Persistent slow return to baseline
  - Long-term variability < 5 BPM
  - Tachycardia > 160 BPM
- Recurrent prolonged decelerations (2 or more below 70 BPM for > 90 seconds in 15 minutes)

Patient Management

To use the Clinical Management Protocol Matrix (Table 6-2) once a sensor has been placed, the fetal heart rate tracing is placed into categories listed in Table 6-1.

In Table 6-1, FHR tracings are characterized according to the values of the baseline heart rate, the presence or absence of variability and accelerations, and the presence or absence of decelerations. Typically, the Classification I trace is characterized by a baseline between 110 and 160 BPM, with long-term variability between 5 and 25 BPM, and either no decelerations or only early decelerations.

Table 6-1. Fetal Heart Rate Classification

FHR Classification	FHR Criteria
I	**Reassuring Group** Any FHR pattern which did not meet criteria for groups II or III.
II	**Non-Reassuring Group** *Any one of the following for > 15 minutes:* 1. Persistent late decelerations (> 50% of contractions) 2. Sinusoidal pattern[a] 3. Variable decelerations with one or more of the following: • A relative drop of ≥ 70 BPM or an absolute drop to ≤ 70 BPM for > 60 sec.[b] • Persistent slow return to baseline • Long term variability < 5 BPM[c] • Tachycardia > 160 BPM 4. Recurrent prolonged decelerations (2 or more below 70 BPM for > 90 seconds) *Any one of the following for > 60 minutes:* 1. Tachycardia > 160 BPM with long term variability < 5 BPM 2. Persistent decreased variability (≤ 5 BPM for > 60 minutes)[c]
III	**Ominous Group** Prolonged deceleration to < 70 BPM for > 7 minutes

a *A sinusoidal pattern was defined as regular oscillations about the baseline, 5–15 BPM in magnitude, with 2 to 5 cycles per minute on an otherwise normal baseline with absent short-term variability.*

b *Variable decelerations were timed from the beginning of the deceleration to the end of the deceleration (i.e., > 60 seconds in duration).*

c *Decreased variability not otherwise explained by the clinical situation (i.e., narcotic administration).*

Patients are managed according to a clinical management protocol guided by the combination of FHR classification and fetal oxygen saturation data. The clinical management protocol is described in Table 6-2.

Table 6-2. Clinical Management Protocol Matrix

FHR Pattern Group	FHR and $FSpO_2$	
	SpO_2 Not Reassuring[a]	SpO_2 Reassuring[b]
Class I: Reassuring FHR	Continue labor unless otherwise indicated[c]	Continue labor unless otherwise indicated[c]
Class II: Non-reassuring FHR	Evaluate and manage non-reassuring FHR	Continue labor unless otherwise indicated[c]
Class III: Ominous FHR	Deliver for fetal distress	Deliver for fetal distress

a *SpO_2 Not Reassuring = SpO_2 remains < 30% between contractions, or no value available despite sensor adjustment.*

b *SpO_2 Reassuring = SpO_2 returns to a value of 30% between contractions.*

c *All corrective non-operative measures are allowed as in protocol text in Figure 6-1.*

In Table 6-2, the clinical management procedure for patients using the combination of FHR and fetal oxygen saturation ($FSpO_2$) is given in the right hand two columns according to the intersection of the FHR tracing (row), and the $FSpO_2$ condition (column). See text for details on actions to be taken when the decision procedure calls for "Evaluate and manage non-reassuring FHR" or "Deliver for fetal distress".

When the action called for in Table 6-2 is "Evaluate and manage non-reassuring FHR", the clinician should execute a series of escalating maneuvers intended to improve fetal oxygenation in an attempt to correct the condition(s) which triggered the abnormal state. The maneuvers include:

- Maternal repositioning to achieve uterine displacement
- Hydration
- Correct hypotension
- Tocolytic for hypertonic contractions
- Maternal oxygen
- Amnio-infusion
- Assessment and correction of oxytocin drug dose

In addition, if no $FSpO_2$ value is being displayed, the clinician should adjust the sensor in an attempt to optimize placement.

If these maneuvers correct the indication for an intervention, the action listed corresponding to the **corrected conditions** determines the intervention level. Thus, if the protocol matrix (Table 6-2) indicates "Deliver for fetal distress", but the maneuvers taken by the bedside clinician correct the FHR and/or $FSpO_2$ such that the indicated action changes to "Continue labor unless otherwise indicated", the appropriate action becomes "Continue labor unless otherwise indicated".

If the protocol matrix following the corrective maneuvers still indicates "Deliver for fetal distress", the fetus should be delivered as soon as practical by whatever means judged appropriate.

If the protocol matrix following the corrective maneuvers still indicates "Evaluate and manage non-reassuring FHR", the clinician uses the evaluation protocol described in Figure 6-1 to obtain additional information regarding fetal well-being. In addition, any of the above non-operative measures are allowed when the status is "Continue labor unless otherwise indicated".

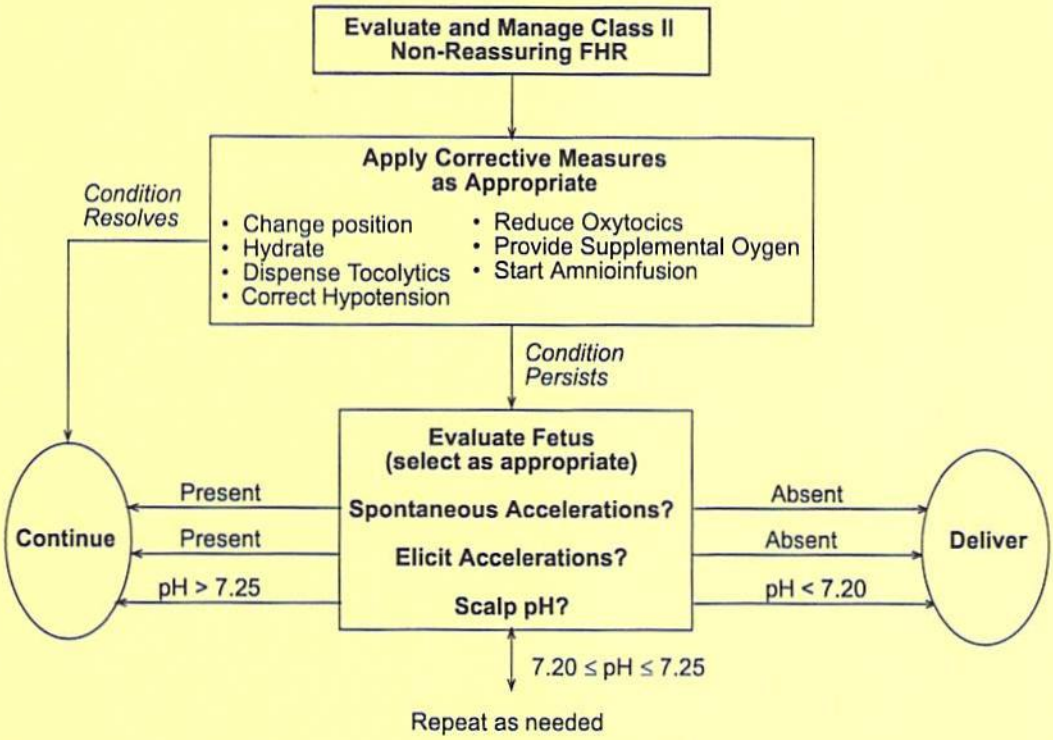


Figure 6-1. Fetal Evaluation Protocol

System Overview

System Components

The fetal oxygen saturation monitoring system consists of three components:

- Corometrics Maternal/Fetal Monitor with built-in fetal pulse oximetry
- Corometrics Fetal Patient Module
- Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14)

Corometrics Maternal/Fetal Monitor with Built-In Fetal Pulse Oximetry

Hardware and software within the monitor process the signal to determine the oxygen saturation of the fetus and assess the quality of the optical signals. The values of saturation and optical signal quality are displayed on the monitor's front panel (along with other indicators), are printed on the monitor's strip chart paper, and are communicated to optional external equipment via serial ports.

Corometrics Fetal Patient Module

Figure 6-2 allows you to become familiar with the Corometrics Fetal Patient Module prior to using it.

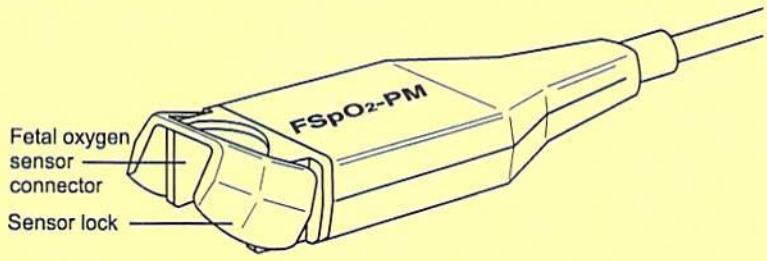


Figure 6-2. Corometrics Fetal Patient Module

Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14)

Figure 6-3 allows you to become familiar with the sensor prior to using it.

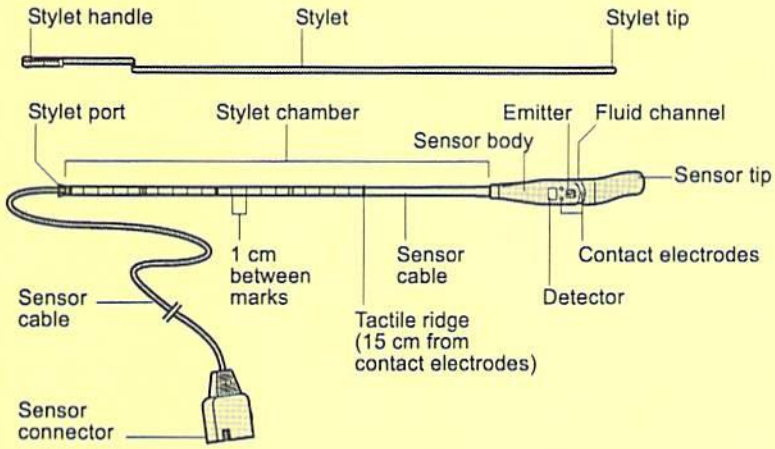


Figure 6-3. Fetal Oxygen Sensor

FSpO$_2$ Monitoring Theory

The monitor measures the fetal oxygen saturation using the principles of spectrophotometry and plethysmography. The sensor is comprised of two light-emitting diodes (LEDs) which are the emitters, and one photodiode which is the detector. One LED emits red light and the other infrared, into the fetus' skin. The detector receives the amount of light that is not absorbed at the sensor site and the monitor uses the relative absorption of red and infrared to compute the percentage of functional hemoglobin that is saturated with oxygen.

Two averaging modes (or response times) are available.

Corometrics 120 F-Series User Interface

This section applies to Corometrics 120 F-Series Monitors only. For convenience, the $FSpO_2$ parameter user interface is summarized in this chapter. You should refer to the operator's manual specific to your monitor for additional information.

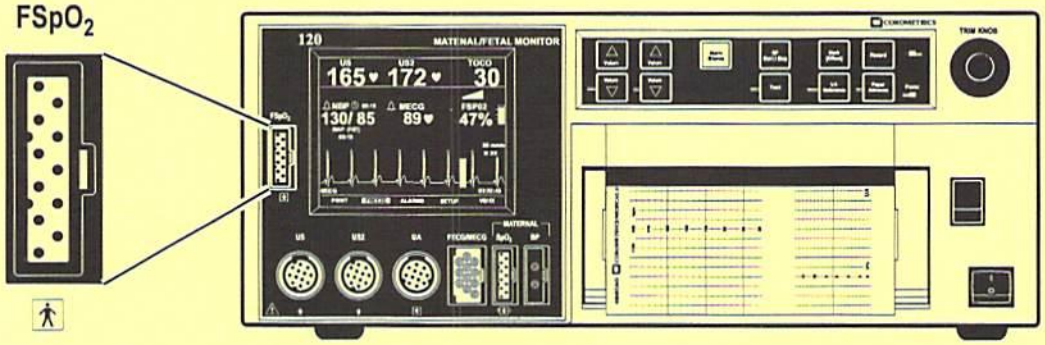


Figure 6-4. 120 F-Series Front Panel

FSpO2 Connector

The FSpO2 connector is a light blue receptacle which accepts a 120 Series Fetal Patient Module cable. Use only Nellcor OxiFirst Fetal Oxygen Sensors (Series FS14) with this monitor.

$FSpO_2$ Display Area

The FSpO2 Display Area is summarized by Figure 6-5 and Table 6-3.

Figure 6-5. $FSpO_2$ Display Area

Table 6-3. $FSpO_2$ Display	
Name	**Description**
$FSpO_2$ Value	This three-digit display indicates the $FSpO_2$ level calculated form qualified optical pulses.
$FSpO_2$ Mode Title	The **$FSpO_2$** title indicates that *fetal* oxygen saturation monitoring is in progress.
Signal Quality Indicator	This indicator shows the average signal quality of pulses being detected at the sensor site according to a software algorithm in the 120 F-Series Monitor. The presence of all ten bars represents fetal pulses with consistently high signal quality for $FSpO_2$ measurement. Fewer bars represents diminished signal quality. The absence of bars represents a lack of fetal pulses with acceptable signal quality.
Pulse Amplitude Indicator	This vertical bar qualitatively indicates pulse amplitude at the sensor site.

A status icon may appear above the %$FSpO_2$ value to provide additional information. Usually the message area will be blank; however, the icons representing **Sensor Unplugged**, **Sensor Lifted**, or **Searching for Fetal Pulse** can appear. Refer to Table 6-4.

Table 6-4. $FSpO_2$ Status Icons	
Name	**Description**
Sensor Unplugged	This icon appears whenever: the $FSpO_2$ sensor is disconnected from the fetal patient module cable; when the fetal patient module cable is disconnected from the monitor; or when an invalid $FSpO_2$ sensor is connected to the fetal patient module cable.
Sensor Lifted	This icon appears whenever the sensor is not making adequate contact at the sensor site on the fetus.
Pulse Search	This icon is displayed when the monitor is attempting to locate the fetal pulse. During successful monitoring, the message area is blank.

Single Versus Dual $FSpO_2$ Monitoring

If $FSpO_2$ is monitored while $MSpO_2$ is inactive, $FSpO_2$ displays underneath uterine activity. Refer to Figure 6-6. However, when dual SpO_2 monitoring occurs, $MSpO_2$ displays here while $FSpO_2$ information moves down next to the waveform directly below $MSpO_2$. Any waveform labels (speed, lead, scale) move to the left of the $FSpO_2$ area. Refer to Figure 6-7.

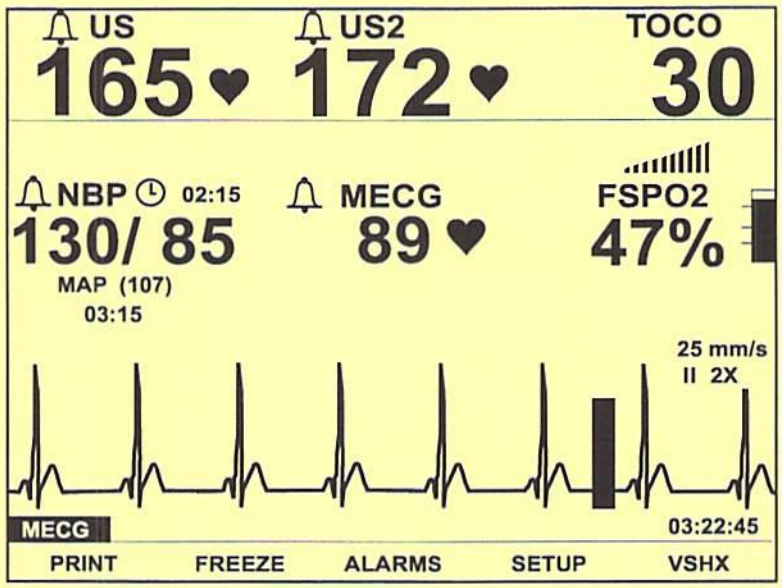


Figure 6-6. Display of Fetal Pulse Oximetry

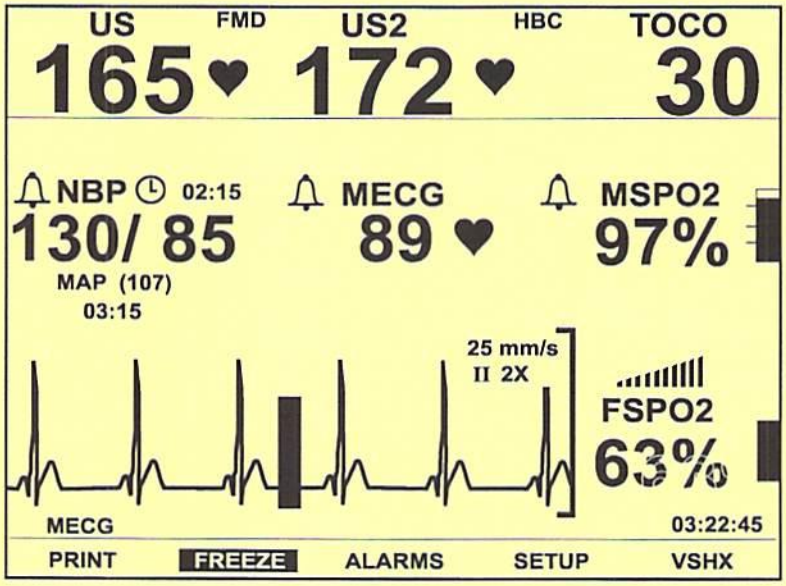


Figure 6-7. Simultaneous Display of Fetal and Maternal Pulse Oximetry

Patient Application

Equipment Required

You will need the following items:

Nellcor OxiFirst Fetal Oxygen Sensor (Series FS14)
Corometrics Fetal Patient Module for use with Nellcor Fetal Sensors
Sterile, Water Soluble Obstetrical Lubricant (optional), such as K-Y Jelly

IMPORTANT
Refer to your monitor's operator's manual for setup and configuration instructions.

Procedure

1. Explain procedure to the patient, including the possibility of discomfort with sensor placement and a discussion of possible adverse events. (The most frequent neonatal adverse events reported in the clinical study included ecchymosis, accidental injury, perinatal disorder, jaundice, and dyspnea. Included in the category of "perinatal disorder" was temperature instability and symptoms of respiratory distress. Refer to the "Information for Prescribers" for more details about adverse events.)
2. Open the end of the sensor package that contains the sensor connector.

IMPORTANT
STERILITY—Expose sensor connector only. Leave the sterile sensor in the package until ready for placement.

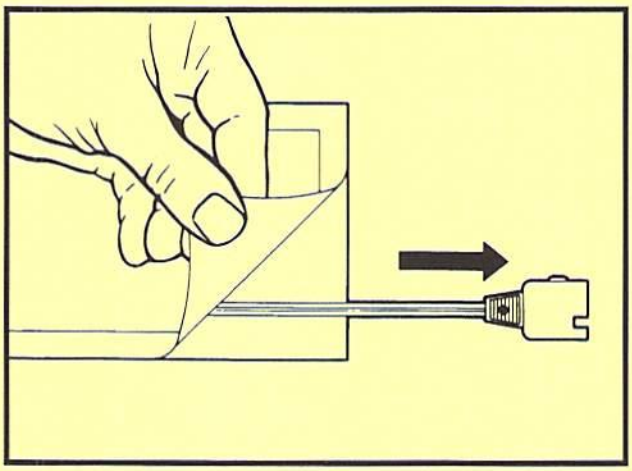


Figure 6-8. Exposing the Sensor Connector

3. Connect the sensor assembly to the fetal patient module:

   a. Ensure the plastic hinged cover is in the unlocked position (perpendicular to the connector).

   b. Insert the male 9-pin male D-type connector on the sensor assembly into the 9-pin female D-type plug on the fetal patient module.

   c. Position the plastic hinged cover in the locked position to prevent accidental cable disconnection.

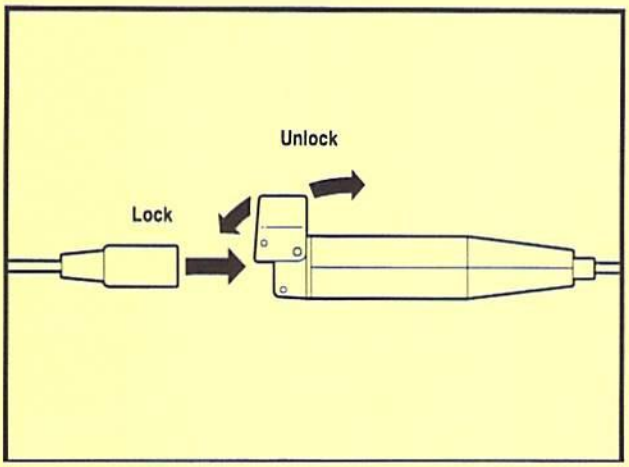


Figure 6-9. Connecting the sensor assembly to the patient module
(*Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.*)

4. Plug the fetal patient module cable into the **FSpO₂** connector on the monitor.

5. Ensure that the red emitter located within the sensor body illuminates. If it does not, use a new sensor.

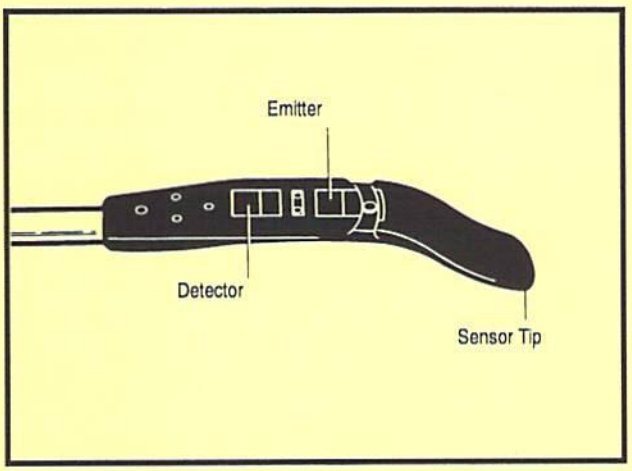


Figure 6-10. Checking the red emitter

6. Determine the position of the fetus. This is most helpful if cervical dilatation is not sufficiently advanced to allow for identification of the fetal cranial landmarks.

NOTE: The fetal oxygen sensor is intended for use on a singleton fetus in the vertex presentation.

7. Put on sterile gloves.

8. Perform a vaginal exam to determine dilatation, station, and fetal position to ascertain the optimal site for sensor introduction. If the head is too high (–2 station or higher), it is unlikely that a signal will be detected due to inadequate contact. If the head is at –1 station or below, the ability to obtain contact and a signal is improved. See Figure 6-11.

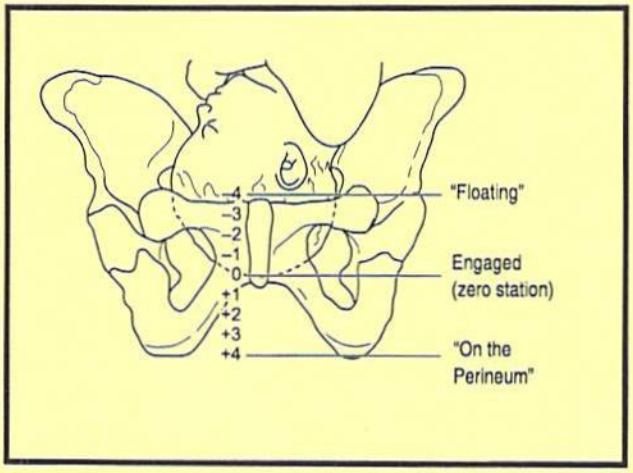


Figure 6-11. Determining the fetal position
(*Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.*)

NOTE: If a lubricant is to be used to aid in sensor placement, use only a sterile, water soluble obstetrical lubricant, such as K-Y Jelly.

9. Determine the optimal sensor site relative to head position. The optimal sensor site is on the cheek/temple area of the fetal head as shown in Figure 6-12. It is preferable to locate the sensor on the side of the fetal head facing the maternal spine (posterior cheek/temple area). This location can be determined by identifying the sagittal suture and one or, ideally, both of the fontanels.

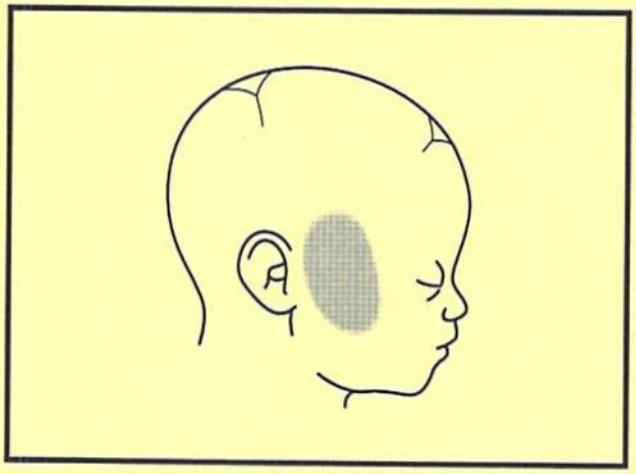


Figure 6-12. Determining the optimal sensor site
(*Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.*)

10. Using sterile technique, remove the sensor from the package.

NOTE: Sensor placement should be attempted between contractions. If a contraction occurs during insertion of the sensor, stop the procedure. Wait for the contraction to end, then proceed with sensor placement. It is not necessary to remove the partially inserted sensor while waiting for the contraction to end.

11. Introduce the sensor at the optimum site relative to head position and depth. It is preferable to introduce the sensor on the side of the head facing the maternal spine (posterior cheek).

CAUTION
FETAL BRADYCARDIA—If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.

12. Hold gloved fingers under sensor tip.

NOTE: Some amniotic fluid may be lost during sensor insertion or during sensor repositions. This may be observed more frequently when an intrauterine pressure catheter has been inserted.

13. Introduce the sensor so that the tip of the sensor is at the midpoint of the sagittal suture. Ensure sensor optics are facing the fetus.

NOTE: If it is difficult to pass the sensor under the cervix, move the sensor to an easier entry location, insert about 3 cm, then, with the gloved examining fingers still in contact with the sensor, guide the sensor around to the desired location.

14. Guide the sensor through the cervical os along the gloved examining fingers approximately perpendicular to the sagittal suture, but slightly towards the anterior fontanel (see Figure 6-13, Figure 6-14, and Figure 6-15). This should align the sensor with the fetal cheek.

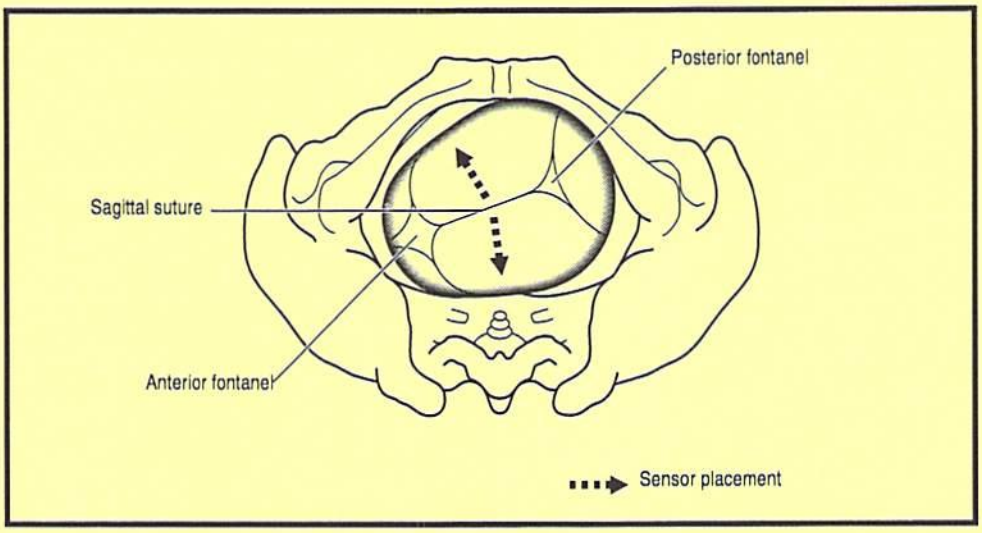


Figure 6-13. Left Occipital-Anterior Position
(*Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.*)

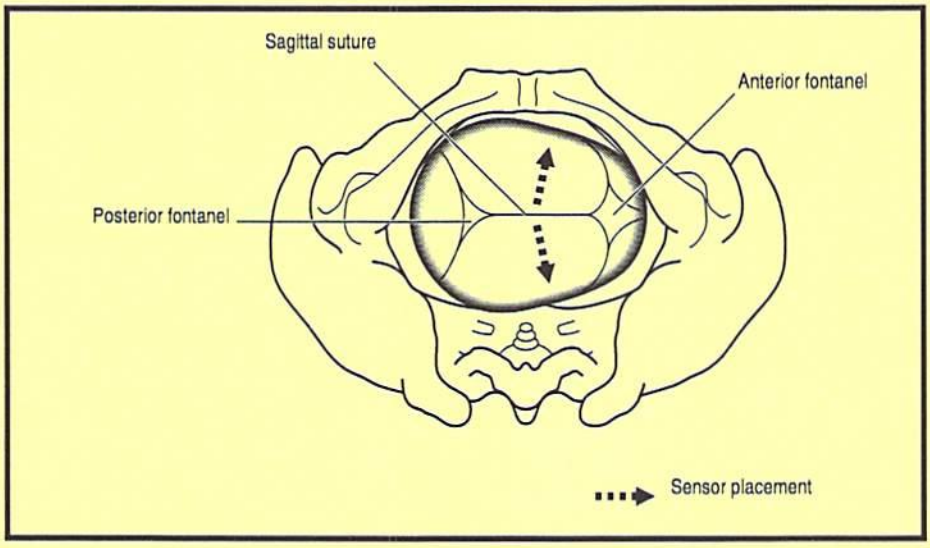


Figure 6-14. Right Occipital-Transverse Position
(*Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.*)

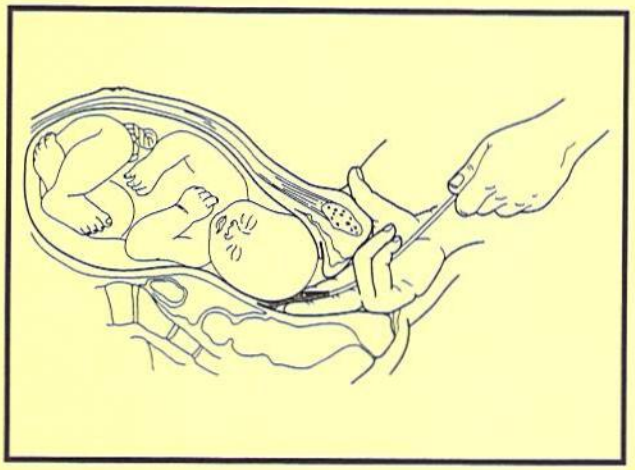


Figure 6-15. Inserting the sensor
(Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.)

15. Insert the sensor until the 15 cm tactile ridge is felt at the midpoint of the presenting part. This corresponds to the tactile ridge crossing the tip of the examining fingers. See Figure 6-16.

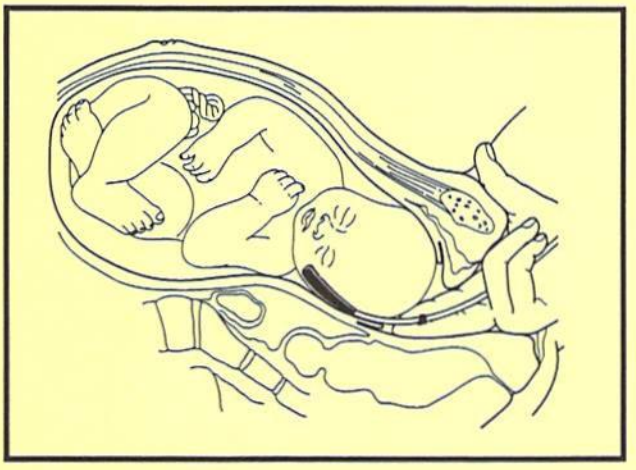


Figure 6-16. Positioning the sensor
(Reprinted courtesy of Nellcor Puritan Bennett, Pleasanton, CA.)

NOTE: At dilatations of 7 cm or greater, resistance often indicates that the sensor is in the vagina rather than under the cervix.

CAUTION
RESISTANCE—Do not force the sensor. If resistance is felt, guide the sensor to a more satisfactory site and continue with placement, if possible. An ear may be the source of resistance, indicating that the sensor placement should be slightly forward and away from the posterior fontanel.

NOTE: The sensor cable mark should be approximately 25–27 cm at the introitus if the fetus is in –2 station.

16. Slowly advance the sensor another 3 or 4 cm to ensure that the LEDs and photodetector are positioned well beyond the fetal presenting part and hair.

17. Withdraw the sensor in 1-cm increments to bring it back on to the preferred monitoring area of the fetal cheek. Observe all indicators and displays on the monitor with each 1-cm move to determine the progress towards positioning the sensor in an optimal location.

    When the Sensor Lifted indicator is not illuminated, remove the stylet with the opposite hand, while continuing to hold the sensor in position with gloved fingers.

> **CAUTION**
> STYLET INSERTION—Do not re-insert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may result in maternal injury.

18. Continue to hold the sensor in position with gloved fingers while observing the $FSpO_2$ area of the monitor display:

    a. If the Sensor Lifted indicator)→▮ reappears on the monitor's display, withdraw the sensor in 1-cm increments until contact is achieved. You should not have to withdraw the sensor more than 3 to 4 cm.

    If you have withdrawn it more than 4 cm and still do not have contact, the sensor may be over hair, or there may be vernix covering the contact reference electrode in the fluid channel.

    Re-assess sensor placement relative to fetal head position, and re-assess sensor depth relative to fetal station by noting the centimeter mark at the introitus.

    After re-assessing fetal position and fetal station, withdraw the sensor head to the edge of the cervical lip and reinsert the sensor until the tactile ridge is at the midpoint of the presenting part. Slowly advance the sensor an additional 3 to 4 cm and begin again to slowly withdraw in 1-cm increments.

    b. If the Sensor Lifted indicator)→▮ disappears, indicating that contact has been achieved, hold the sensor in place with gloved fingers for about 15 seconds until the sensor seats itself.

    c. Note the cm mark on the stylet chamber relative to the introitus.

    d. If you are still not successful in achieving sensor contact and $FSpO_2$ display after one to two attempts to reposition, remove sensor and inspect it for the presence of vernix.

    e. The appearance of heavy vernix on the sensor or in the fluid channel may indicate that the sensor was placed over hair rather than on the cheek or temple area. Vernix over the cheek or temple is unusual in the full-term fetus, but, if present, may preclude $FSpO_2$ monitoring for that specific fetus.

NOTE: During sensor insertion and before the tactile ridge reaches the midpoint of the presenting part, the Sensor Lifted indicator may disappear from the display when the contact electrodes touch maternal tissue (vaginal or cervical). However, unless the tactile ridge has reached the midpoint of the presenting part, the fact that the indicator is not displayed does not necessarily indicate proper contact with the fetal skin.

f. Watch for activity on the monitor Pulse Amplitude bar and Signal Quality indicators to provide feedback on the quality and relative strength of the fetal pulses that are being detected by the sensor.

The Signal Quality indicator should slowly climb from one segment on the display to five or more segments before an initial $FSpO_2$ value will be displayed on the monitor.

NOTE: Whenever it is necessary to reposition the sensor, do not withdraw the sensor completely. Withdraw the sensor body to the cervical lip. It can then be moved around easily to a new position with gloved examining fingers.

g. If Signal Quality is two to three segments only, the sensor is not in a location that will continuously provide fetal pulses of sufficient quality for $FSpO_2$ measurement.

Reassess sensor placement relative to fetal head position and reassess sensor depth relative to fetal station, then adjust, or reposition sensor for better pulse signal quality. Usually the sensor only needs to be advanced or withdrawn (adjustment) a centimeter or two.

However, it may be necessary to completely reposition the sensor by withdrawing the sensor head back to the cervical lip and reinserting, as described in step 18a.

h. Try to achieve a stable signal quality of seven or more segments, which indicates optimal positioning on the fetal face or temple.

If signal quality remains below five bars for two to three minutes after the initial placement, it is unlikely that $FSpO_2$ will be displayed, even if contact has been achieved. Reassess sensor placement relative to fetal head position and reassess sensor depth relative to fetal station, then attempt to reposition sensor for more consistent fetal pulses with better signal quality.

i. After the sensor has been optimally positioned, the monitor should display data within two to three minutes. Observe that $FSpO_2$ values are displayed. If data is displayed within two to three minutes, and signal quality is stable at five or more segments, leave the sensor positioned as is and remove examining fingers.

19. When the head rotates as it descends, the sensor may need to be adjusted or repositioned.

a. Observe the monitor periodically throughout the course of labor to determine whether or not the sensor needs adjusting or repositioning.

b. When the sensor is in optimal position on the fetus, between contractions, you should observe:

- Nearly continuous display of $FSpO_2$
- No illumination of the Sensor Lifted indicator
- Signal quality stable at seven or more segments
- Rhythmic ramping of the Pulse Amplitude bar

c. Occasionally during uterine contractions, some or all of the parameters listed above may be momentarily lost from the display due to normal forces applied to the fetus and sensor. Always wait for a few seconds after a contraction subsides before attempting to adjust or reposition the sensor, as displayed values may return.

d. If $FSpO_2$ is no longer continuously displayed between contractions, observe the monitor to determine status of the Sensor Lifted, Pulse Amplitude, and Signal Quality indicators.

e. If the Sensor Lifted indicator is illuminated, note cm mark at introitus to determine any change in relative depth of the sensor since it was last adjusted.

   Slowly withdraw or advance the sensor in 1-cm increments based on the status of labor progress and the cm mark at the introitus until contact is re-established with the fetus.

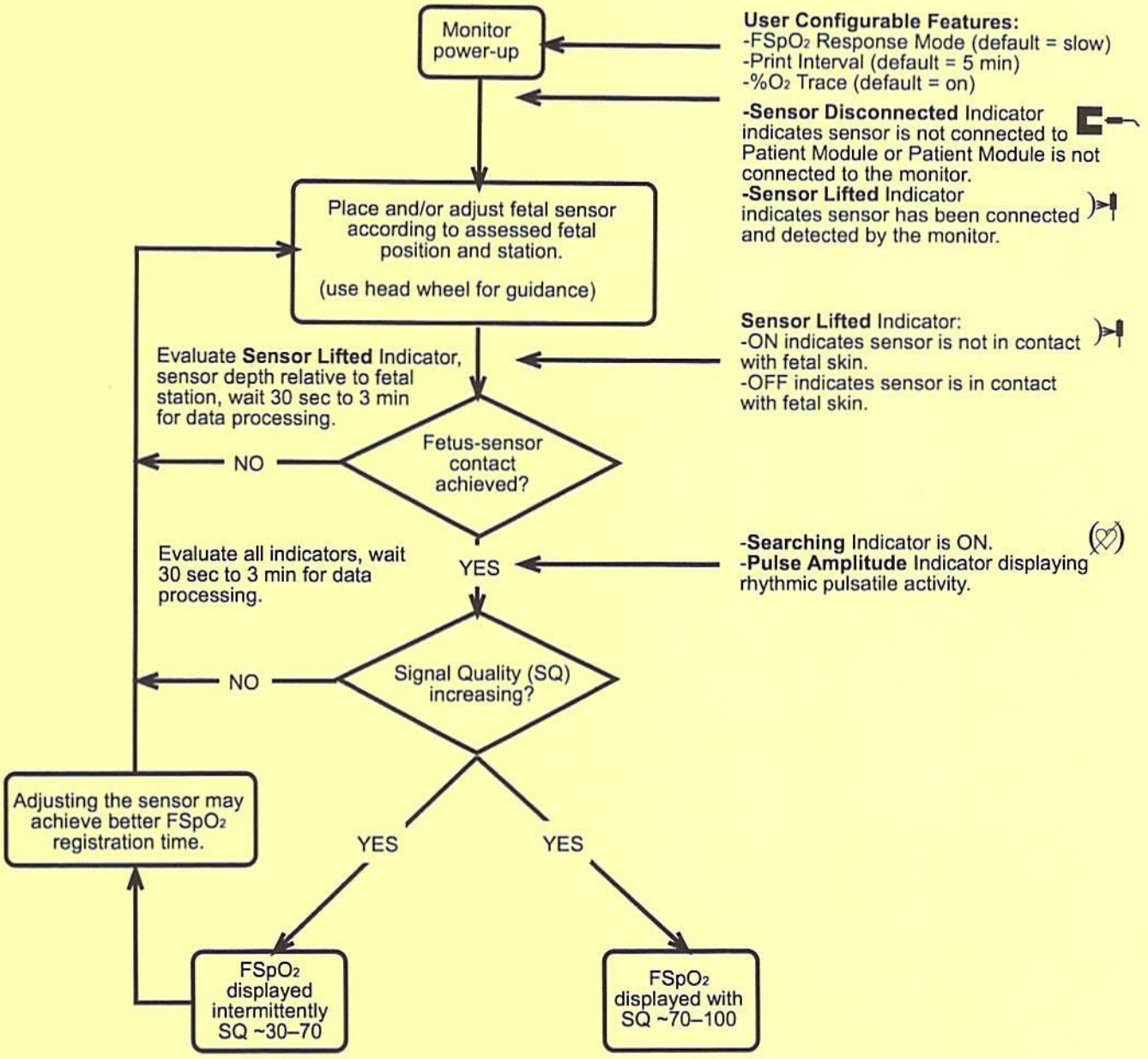
f. Follow steps 18f through 18i related to signal quality to re-establish an optimal sensor placement following sensor adjustment/repositioning.

g. If the Sensor Lifted indicator is not illuminated, and $FSpO_2$ is no longer being continuously displayed between contractions, it is likely that signal quality has degraded and the Signal Quality indicator has dropped below five segments. Adjust the sensor slightly or withdraw/advance the sensor in 1-cm increments until a stable signal quality of five segments or more is re-established.

20. Note that the $\%FSpO_2$ trend prints on the lower (or right) grid of the strip chart paper. (Some monitors allow you to disable the printing of the $\%FSpO_2$ trend.)

21. The sensor may be left in place during normal, unassisted vaginal delivery.

WARNING
SENSOR REMOVAL—Remove the sensor prior to vacuum extraction, forceps delivery, or Cesarean delivery.


Monitor power-up
User Configurable Features:
-FSpO2 Response Mode (default = slow)
-Print Interval (default = 5 min)
-%O2 Trace (default = on)
-Sensor Disconnected Indicator indicates sensor is not connected to Patient Module or Patient Module is not connected to the monitor.
-Sensor Lifted Indicator indicates sensor has been connected and detected by the monitor.
Place and/or adjust fetal sensor according to assessed fetal position and station.
(use head wheel for guidance)
Sensor Lifted Indicator:
-ON indicates sensor is not in contact with fetal skin.
-OFF indicates sensor is in contact with fetal skin.
Evaluate Sensor Lifted Indicator, sensor depth relative to fetal station, wait 30 sec to 3 min for data processing.
Fetus-sensor contact achieved?
NO
YES
-Searching Indicator is ON.
-Pulse Amplitude Indicator displaying rhythmic pulsatile activity.
Evaluate all indicators, wait 30 sec to 3 min for data processing.
Signal Quality (SQ) increasing?
NO
YES
YES
Adjusting the sensor may achieve better FSpO2 registration time.
FSpO2 displayed intermittently SQ ~30–70
FSpO2 displayed with SQ ~70–100

Non-Optimal Sensor Site
-Signal Quality fluctuating between 30-70
-Non-rhythmic pulses seen on Pulse Amplitude Indicator
-Sensor depth does not correlate with fetal station.

Optimal Sensor Site
-Sensor Lifted Indicator is never ON
-Signal Quality is consistently above 70.
-Rhythmic pulses seen on Pulse Amplitude Indicator.

Figure 6-17. Sensor Placement Flowchart

For your notes

Chapter 7

MECG Monitoring

This sections explains how the maternal heart rate is measured via MECG. For information about how the maternal pulse rate is derived from NBP and $MSpO_2$ monitoring, refer to Chapter 8, "Maternal Non-Invasive Blood Pressure Monitoring" and *Chapter 9, "Maternal Pulse Oximetry Monitoring"*.

This chapter describes the following:

Overview 7-2
Safety Precautions 7-3
Patient Application 7-4

Overview

MHR Data

Refer to your monitor's operator's manual for information about which parameters are displayed, printed, and used in evaluating alarm conditions. (Not all monitors provide alarms.)

Theory and Methodology

The maternal heart rate (MHR) is measured using signals obtained via electrodes placed on the maternal chest. When MECG is employed, the maternal heart rate is computed on a beat-to-beat basis using the R-to-R time interval on the maternal QRS complex.

About the Connector

Some monitors have a single **ECG** connector that is used for either FECG or MECG monitoring. Other monitors have an **MECG** connector dedicated to MECG monitoring. For ease of reference in this manual, the **MECG** label is used. Refer to your monitor's operator's manual for the actual connector label(s). (Not all monitors include MECG or FECG monitoring.)

Safety Precautions

The following safety information applies to patients with pacemakers.

WARNINGS

FALSE ALARMS—False low heart rate alarms or false asystole may result with certain pacemakers because of electrical overshoot. (Not all monitors provide alarms.)

FALSE COUNTING—Be aware that a pacer spike could be falsely counted as a QRS complex during asystole.

INTERFERENCE—Interference caused by electrosurgical or diathermy instruments will affect the proper operation of the ECG section of a maternal/fetal monitor.

PACEMAKER SPIKE—Do not diagnostically interpret the pacemaker spike size and shape; the spike may be attenuated by the module in order to be displayed or printed. (Not all monitors include waveform display/ printing.)

PATIENT OBSERVATION—Keep pacemaker patients under close observation.

Patient Application

This section applies to monitoring the maternal heart rate using MECG electrodes.

Equipment Required

You will need the following items:

Three (3) Disposable ECG Electrodes (Round Foam, Cat. No. [REF] 9431-004)
Maternal ECG Cable with three leadwires (permanently attached or detachable; snap or grabber)
Alcohol Swabs
Garment Clips
Tape

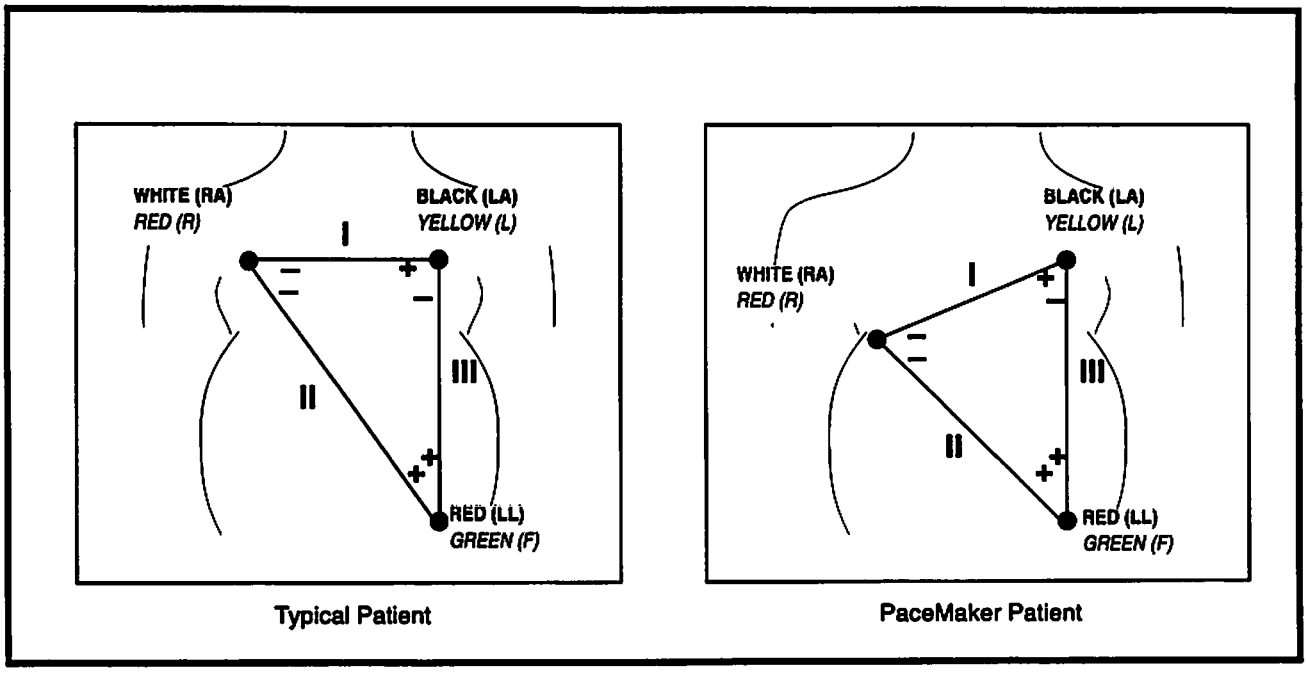
About Disposable Electrodes

The following information is useful in maintaining a quality ECG signal:

- Check expiration dates on electrode packaging. Outdated electrodes may be dry; dry electrodes may result in increased artifact.
- Always check the center (gelled portion) of the electrodes to ensure the surface is moist.
- Be aware of climate and storage effects on electrodes. Excess heat or moisture could affect the integrity of the adhesive.
- Replace electrodes every 24–48 hours. Over the course of this time, the electrode gel will start to dry out and the adhesive will age. In addition, patients with sensitive skin may become irritated by the gel or adhesive resulting in discomfort.
- Change the electrodes if they do not completely adhere to the patient's chest.
- If skin irritation develops from the electrodes, change the placement and/or change to another type of electrode.

Procedure

1. Plug the MECG cable into the **MECG** connector on the monitor.
2. Determine the appropriate electrode sites. (See Figure 7-1.) Some monitors allow you to select the desired ECG lead configuration: I, II, or III. Lead I refers to the potential between the left arm and the right arm. Lead II refers to the potential between the right arm and left leg. Lead III refers to the potential between the left arm and the left leg.
   - ***Typical Patient:*** The conventional RA/R, LA/L, LL/F attachment sites are used.
   - ***Pacemaker Patient:*** For pacemaker patients, the RA/R electrode may need to be re-positioned to modify detection of the electrical signals generated by a pacemaker. If a sufficient signal cannot be obtained using the conventional RA/R attachment site, try moving the electrode lower on the chest.



NOTE: AHA label listed first; IEC label *italicized* beneath

Figure 7-1. Electrode Placement

1. Using a dry washcloth, gently rub skin surface at sites to remove dead skin cells.
2. Thoroughly cleanse the sites with alcohol or a mild soap and water solution. Be sure to remove all oily residue, dead skin cells, and abrasives. Leftover abrasion particles can be a source of noise (artifact).
3. Dry the skin completely before applying the electrodes.

NOTE: If using snap leadwires, be sure to snap each leadwire on an electrode *before* applying the electrode to the patient. If using grabber leadwires, apply the electrodes to the patient, then attach each leadwire to the electrode.

4. Remove the protective cover and apply the electrodes as illustrated in step 2. Do not press down on the center; secure by pressing on the paper edges.

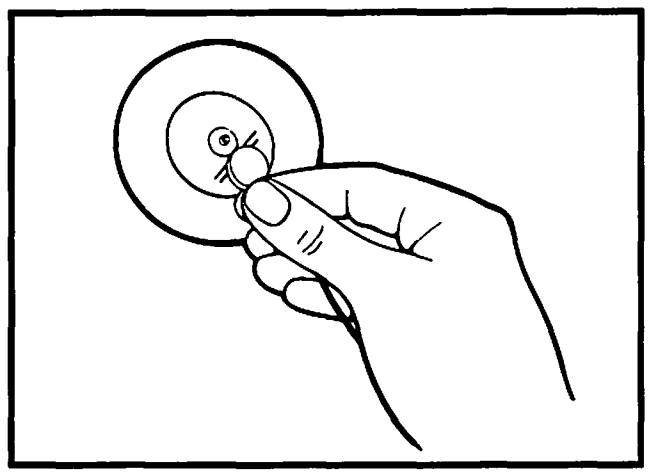


Figure 7-2. Attaching leadwires to electrodes

5. Stabilize each electrode and leadwire with a leadwire stress loop near the electrode. Tape the stress loop to the patient. A secured stress loop prevents leadwire rotation about the electrode snap, leadwire tugging at the electrode, and ECG artifact.

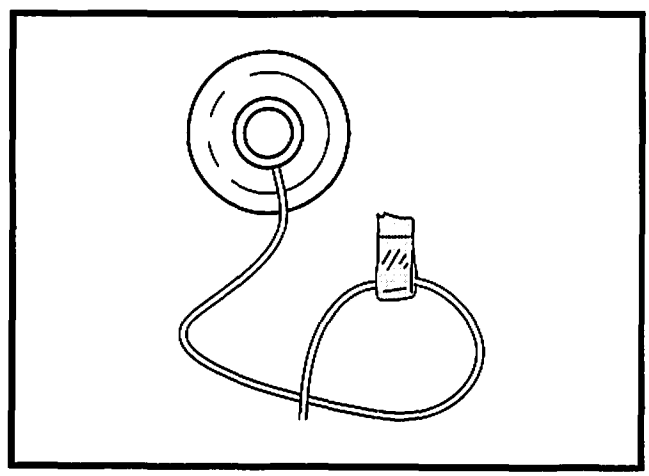


Figure 7-3. Adding a Leadwire Stress Loop

6. Attach the leadwires to the MECG cable (if detachable).
7. Secure the cable to the patient's gown with the garment clip. Ensure there is no tension on the wires.
8. Check the maternal pulse.
9. Note that the MHR shows on the monitor's display and the MHR trace prints on the top (or left) grid of the strip chart paper. Some monitors also display/print the MECG waveform.

NOTE: On some monitors, you can disable displaying of the MECG value and/or printing of the MECG trace. Refer to your monitor's operator's manual for more information.

CAUTION
WAVEFORM INTERPRETATION—The MECG waveform is not intended for true diagnostic interpretation. This waveform should be used as an adjunct in patient assessment in conjunction with clinical signs and symptoms. (Not all monitors include ECG waveform display/printing.)

For your notes

Chapter 8

Maternal Non-Invasive Blood Pressure Monitoring

A maternal/fetal monitor equipped with a built-in blood pressure module can measure the maternal systolic pressure, diastolic pressure, mean arterial pressure (MAP), and pulse rate. Two operating modes are provided: manual and automatic.

This chapter describes the following:

Safety Precautions 8-2
Oscillometric Theory 8-4
Patient Application 8-5

Safety Precautions

The following safety information applies to non-invasive blood pressure (NBP) monitoring using a maternal/fetal monitor:

CAUTIONS

ARRHYTHMIAS—When a patient is experiencing arrhythmias during a reading, the accuracy of the pulse determination may be affected or the time needed to complete a measurement may be extended.

CALIBRATION—Do not operate the monitor unless it has been properly calibrated. Inaccurate blood pressure readings may result.

CUFF PLACEMENT—Inaccurate $MSpO_2$ measurements may result if the blood pressure cuff is placed on an extremity with an $MSpO_2$ sensor.

CUFF SIZE—Always measure the limb circumference to ensure that the proper cuff size is selected. Accurate readings depend upon selection of the proper size cuff.

DISPLAY INTERVAL—The time period, in minutes, that a blood pressure reading remains displayed before being automatically erased, depends on the model of the maternal/fetal monitor. Some monitors may continuously display a reading until replaced by a new reading. The display of "old" pressure values may cause confusion. If a patient's condition changes during the time interval between determinations, the monitor will not detect the change or indicate an alarm condition. Blood pressure and pulse can fluctuate greatly between measurements; the monitor does not alert the user (through audio or visual means) to changes in vital signs occurring between measurement cycles.

INTRAVENOUS INFUSION—Do not use the blood pressure cuff on a limb being used for intravenous infusion.

OVERPRESSURE—After the monitor has been calibrated or repaired, perform a final check of the pneumatic system and verify that a pressure greater than 280 mmHg causes an *overpressure* error condition.

CAUTIONS

PATIENT ASSESSMENT—As with any non-invasive oscillometric blood pressure monitor, there are clinical conditions which can affect the accuracy of the measurements obtained. For example, do not use the monitor's NBP feature on a patient experiencing convulsions or attached to a heart/lung machine. In addition, disregard or stop automatic blood pressure determinations which coincide with maternal contractions. Also, be aware that the accuracy of measurements can be affected if readings coincide with maternal contractions.

PULSE RATE COMPARISONS—The pulse rate measured by a monitor's NBP circuitry may differ from the heart rate measured by the monitor's MECG circuitry or another maternal ECG monitor because the monitor's blood pressure module measures peripheral pulses, not electrical signals or contractions of the heart. Occasionally, the electrical signals at the heart do not produce a peripheral pulse. Similarly, if a patient's beat-to-beat pulse amplitude varies significantly, blood pressure and pulse rate readings can be erratic and an alternate measuring method should be used for confirmation.

SHOCK—If a patient is in shock, the low amplitude of the blood pressure waveform makes it difficult for the monitor to accurately determine the systolic and diastolic pressures. If the monitor is unable to determine the blood pressure, the cuff is automatically deflated.

HYDROSTATIC EFFECT—If the cuff is not at heart level, the difference in the reading due to the hydrostatic effect should be noted. (Add the value 1.80 mmHg to the displayed readings for every inch the cuff is above heart level. Subtract the value 1.80 mmHg from the displayed readings for every inch the cuff is below heart level. Document the reading.)

Oscillometric Theory

The monitor automatically measures the maternal systolic pressure, diastolic pressure, mean arterial pressure (MAP), and the pulse rate using the oscillometric technique — the monitor detects and measures pressure oscillations induced in the cuff by movement of the arterial wall.

When a determination is initiated, the cuff is inflated to a suprasystolic pressure, so that the flow of blood through an artery is temporarily stopped. The monitor then incrementally deflates the cuff until blood begins to flow through the artery and induces oscillations in the cuff. The pressure reading at this point is the systolic pressure. The cuff pressure continues to be reduced until the maximum oscillation amplitude is reached. The pressure reading at this time is the MAP. The cuff pressure is further reduced until the oscillation amplitudes are diminished to the point where they become uniform. The point at which they become uniform is the diastolic pressure.

Patient Application

There are two modes of operation for monitoring: manual and automatic. In manual mode, a single determination is made at a time upon activation of a "start/stop" button. (Refer to your monitor's operator's manual for the actual button labels.) In auto mode an indefinite series of determinations are made at defined time intervals.

Equipment Required

You will need the following items:

Blood Pressure Cuff
Air Hose Interconnection Cable

Procedure

1. Select a pressure cuff that is the appropriate size for the patient limb.
2. Ensure that the air hose has the appropriate connectors for mating with tubing on the selected cuff. (For example: single-tube luer vs. dual-tube luer.)

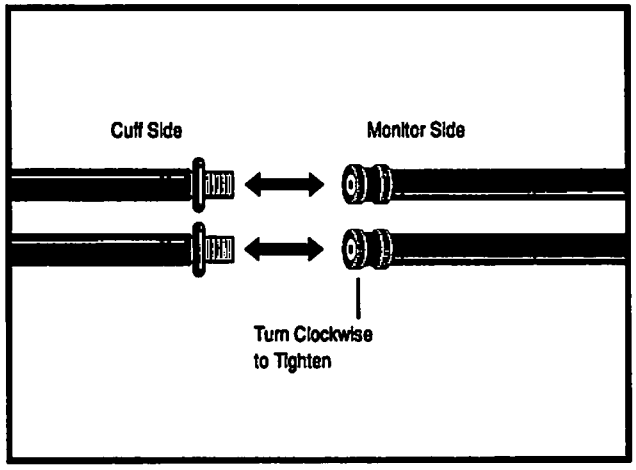


Figure 8-1. Connecting the Air Hose to the Cuff Tubing

3. Attach the air hose to the monitor's **Maternal BP** connector. Ensure the air hose has the appropriate connector for mating with the **Maternal BP** connector.

4. Wrap the cuff around a free limb of the patient, as close to heart level as possible. For reading accuracy, the cuff should be fitted snugly and directly against the patient's skin. Clothing should not come between the patient's skin and the cuff. Proper cuff placement can be gauged by the ability to easily insert two fingers beneath the cuff yet the cuff should be snug enough to prevent it from slipping up or down.

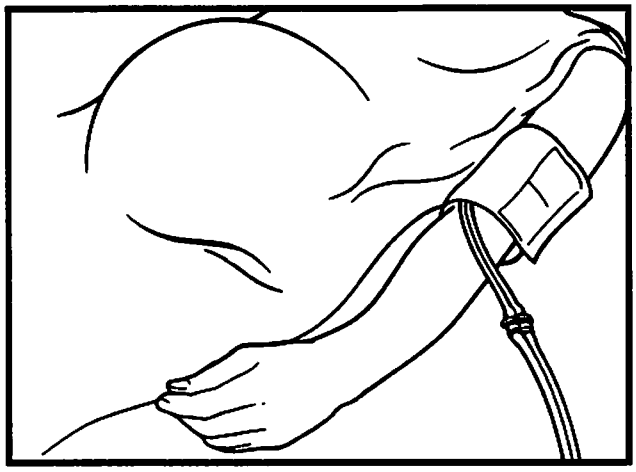


Figure 8-2. Positioning a Blood Pressure Cuff

5. Select the desired mode: manual or automatic. (Refer to your monitor's operator's manual for information about selecting modes and setting any additional BP-related options.)

NOTE: Only take a manual blood pressure measurement in-between contractions—when the uterus is at rest.

- ***Manual Mode:*** Press the monitor's "start" button to activate a manual reading. The cuff will inflate to 160 mmHg. If this initial inflation pressure is insufficient, the unit retries with a higher inflation pressure (+30 mmHg). The instantaneous cuff pressure is displayed in place of the mean arterial pressure area and is indicated by the title **CUFF**.
- ***Automatic Mode:*** Refer to your monitor's operator's manual for information about activating the first automatic reading The first *automatic* determination inflates the cuff to 160 mmHg. For subsequent determinations, the cuff reaches an inflation pressure of 30 mmHg greater than the previously determined systolic pressure value. If this initial inflation pressure is insufficient, the unit retries with a higher inflation pressure (+30 mmHg). The instantaneous cuff pressure is displayed in place of the mean arterial pressure area.

NOTE: If the cuff is not at heart level, the difference in the reading due to the hydrostatic effect should be noted. (Add the value 1.80 mmHg to the displayed readings for every inch the cuff is above heart level. Subtract the value 1.80 mmHg from the displayed readings for every inch the cuff is below heart level. Document the reading.)

6. The blood pressure cuff then begins deflating during which time the monitor is storing the cuff pressure and its corresponding pulse amplitude. The deflation sequence continues until the diastolic pressure is determined or until the cuff pressure has decreased to 7 mmHg.

Venous Return in Auto Mode

Corometrics monitors always wait ***at least 30 seconds*** from the end of one blood pressure determination to the beginning of the next. This provides a minimum time that pressure around the patient's limb is relieved, to allow for venous return. If a determination ends with less than 30 seconds remaining until the next one, that next determination will be cancelled or delayed.

For your notes

Chapter 9

Maternal Pulse Oximetry Monitoring

A maternal/fetal monitor equipped with a built-in $MSpO_2$ module measures the maternal oxygen saturation and pulse rate using the principles of spectrophotometry and plethysmography.

This chapter describes the methods of monitoring each parameter.

Safety Precautions 9-2
Overview 9-4
Patient Application 9-5

Safety Precautions

CAUTIONS

DOUBLE COUNTING—If a patient is receiving tocolytic agents, the bounding effect may cause the pulse wave to have a pronounced dicrotic notch that may occasionally cause double counting of a single beat resulting in a falsely high pulse rate.

MEASUREMENT ACCURACY—Inaccurate measurements may result if the sensor is placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Measurements may be compromised if the sensor is placed on a patient wearing dark-colored nail polish. Remove nail polish prior to sensor application.

PATIENT ASSESSMENT—Do not use the sensor on a patient with known sensitivities or allergic reactions to adhesive tape. Do not use the sensor on a patient who is in shock, has hypotension, severe vasoconstriction or anemia, hypothermia, arterial occlusion proximal to the sensor, or cardiac arrest. Inaccurate measurements may result from incorrect application or use of a sensor; significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin; significant levels of indocyanine green, methylene blue or other intravascular dyes; excessive patient movement; venous pulsations; or electrosurgical interference.

SENSOR APPLICATION—Tissue damage can occur through the incorrect application or use of a sensor. Do not wrap the sensor too tightly or apply supplemental tape.

SENSOR ENVIRONMENT—Do not use the sensor in environments with excessive illumination such as surgical lamps, especially ones with a xenon light source, bilirubin lights, fluorescent lights, infrared heating lamps, or direct sunlight. Signal loss or inaccurate readings can otherwise result.

SENSOR TYPE—Corometrics monitors are designed to use only Nellcor brand adult sensors.

CAUTIONS

SINGLE-PATIENT USE—Do not immerse the sensor in water or cleaning solutions. Each sensor is for single-patient use only. Do not re-sterilize.

VISUAL INSPECTION—Periodically inspect the sensor visually for obvious damage. Do not use a damaged sensor or one with exposed electrical contacts.

WAVEFORM INTERPRETATION—The $MSpO_2$ waveform generated by the monitor is not intended for true diagnostic interpretation. This waveform should be used as an adjunct in patient assessment in conjunction with clinical signs and symptoms. (Not all monitors provide waveform display/printing.)

Overview

Theory

The monitor measures the maternal oxygen saturation and pulse rate using the principles of spectrophotometry and plethysmography. The $MSpO_2$ sensor is comprised of two light-emitting diodes (LEDs) which are the emitters, and one photodiode which is the detector. One LED emits red light and the other infrared into the patient's skin. The detector receives the amount of light that is not absorbed at the sensor site and the monitor uses the relative absorption of red and infrared to compute the functional percentage of hemoglobin that is combined with oxygen. The heart rate is calculated from the pulses measured at the sensor site.

Three averaging modes (or response times) for percentage and rate are available.

Methodology

The maternal oxygen saturation displays as three digits indicating the percentage of oxygen saturation. The pulse amplitude indicator is a vertical bar that qualitatively indicates the pulse amplitude. On some monitors, each pulse beat is indicated with a "beep" that varies in pitch to reflect changes in the oxygen saturation reading. The pitch rises as the saturation values increase; the pitch lowers as the saturation values decrease. (Refer to your monitor's operator's manual for detailed information.)

Patient Application

Equipment Required

You will need the following items:

Nellcor Adult Sensor (D-25 or D-25L Single-Patient Use Sensor recommended and illustrated in this section)
Corometrics Intermediate Cable for use with Nellcor Sensors

Procedure

1. Connect the sensor assembly to the intermediate cable:
   a. Ensure the plastic hinged cover is in the unlocked position (perpendicular to the connector).
   b. Connect the sensor assembly to the intermediate cable assembly.
   c. Position the plastic hinged cover to the locked position to prevent accidental cable disconnection.

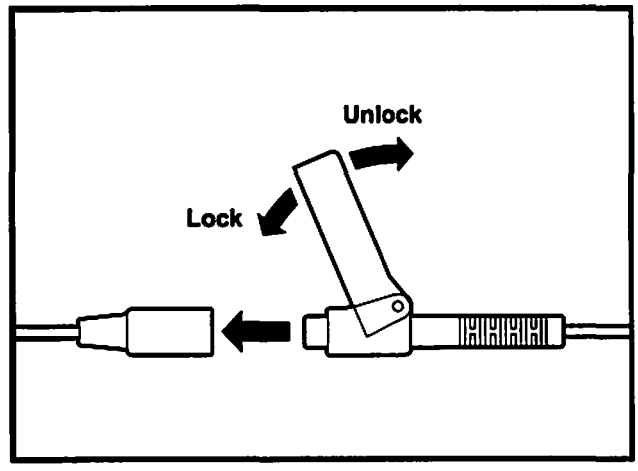


Figure 9-1. Connecting the Sensor Assembly to the Intermediate Cable

2. Plug the intermediate cable assembly into the **Maternal $MSpO_2$** connector on the monitor.
3. Ensure that all $MSpO_2$ setup options are configured appropriately for this patient. (Refer to your monitor's operator's manual.)

4. Remove the plastic backing and locate the transparent windows on the adhesive side. These windows house the optical components.

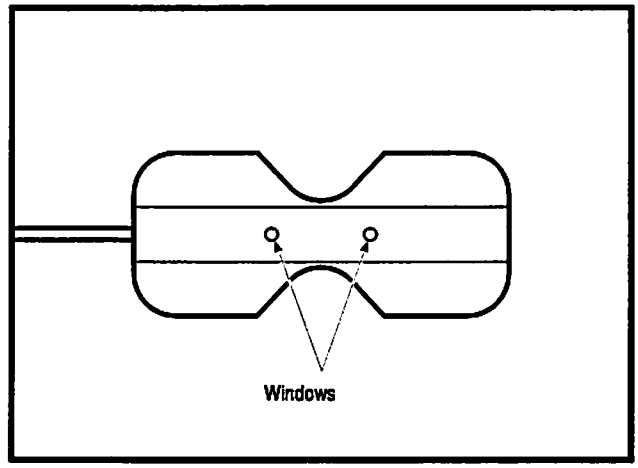


Figure 9-2. Locating the Sensor Windows

5. Orient the sensor so that the dashed line in the middle of the sensor is centered on the tip of the finger.

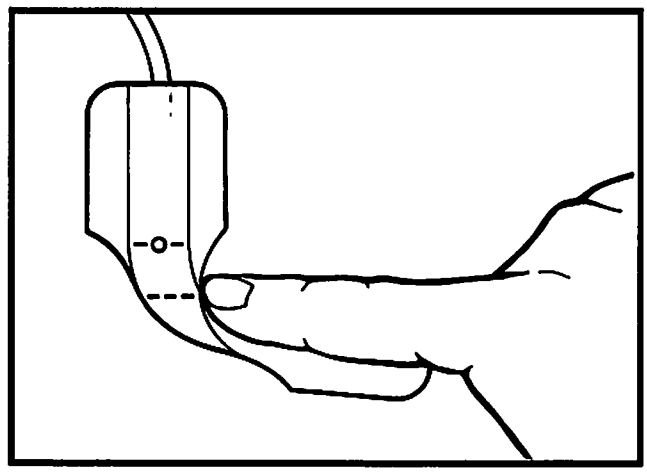


Figure 9-3. Positioning the Sensor

NOTE: The cable must run up the top of the patient's hand.

6. Wrap the adhesive on the non-cable end around the finger.

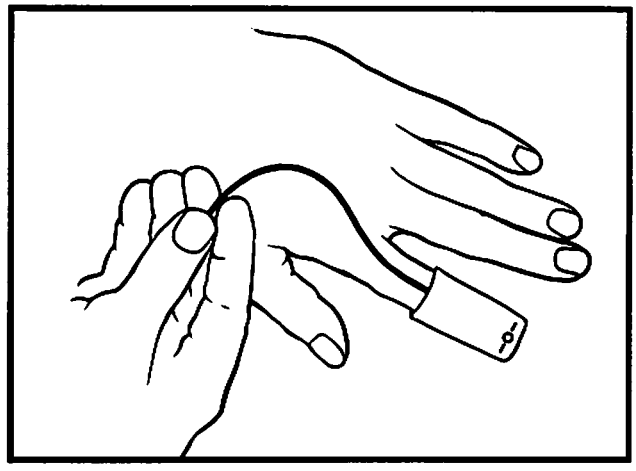


Figure 9-4. Securing the sensor to the finger

7. Fold the cable end over the top of the finger so that the windows are directly opposite each other. Wrap the adhesive securely around the sides of the finger.
8. Begin monitoring. As soon as an acceptable pulse signal is detected, the pulse amplitude indicator reflects the qualitative measurement of the pulse amplitude and the maternal oxygen saturation percentage continuously shows on the monitor's display. In addition, the %MSpO$_2$ trace appears on the bottom (or right) of the strip chart paper. (On some monitors, you can disable printing of the %MSpO$_2$ trace.)

For your notes

MANUAL P/N 15457AA

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